As confidentially submitted to the Securities and Exchange Commission on June 11, 2020.

This Amendment No. 1 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter) ${\bf 2834}$

(Primary Standard Industrial

Classification Code Number)
630 W. Germantown Pike, Suite 215

630 W. Germantown Pike, Suite 215 Plymouth Meeting, PA 19462 Telephone: (484) 539-9800

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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(State or other jurisdiction of

incorporation or organization)

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82-2279923

(I.R.S. Employer Identification No.)

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: AS SOON AS PRACTICABLE AFTER THIS REGISTRATION STATEMENT IS DECLARED EFFECTIVE.

If any of the securities being re	gistered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities
Act of 1933, check the following box.	

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

Indicate by check mark whether the registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth

company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer $\ \square$ Accelerated filer $\ \square$

Non-accelerated filer ⊠

Smaller reporting company $\ oxdot$

Emerging growth company ⊠

If an emerging growth company, that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a) (2)(B) of the Securities Act. \Box

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee(3)
Common Stock, par value \$0.00001 value per share	\$	\$

- (1) Includes the aggregate offering price of common stock that may be sold if the option to purchase additional shares of our common stock granted by the Registrant to the underwriters is exercised. See "Underwriting."
- (2) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended.
- (3) To be paid in connection with the initial public filing of the registration statement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated , 2020.

Shares



Common Stock

This is an initial public offering of shares of common stock of Harmony Biosciences Holdings, Inc.

We are offering shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share of our common stock will be between \$ and \$. We have applied to list our common stock on the Nasdaq under the symbol "HRMY."

We are an "emerging growth company," as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 15 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to Harmony Biosciences Holdings, Inc.	\$	\$

⁽¹⁾ See "Underwriting" for a description of the compensation payable to the underwriters.

To the extent that the underwriters sell more than shares of our common stock, the underwriters have the option to purchase up to an additional shares from us at the initial price to the public less the underwriting discount.

The underwriters expect to deliver the shares of our common stock against payment in New York, New York on , 2020.

Goldman Sachs & Co. LLC	Jefferies	6	Piper Sandlei
	Prospectus dated	, 2020.	

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We and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any related free writing prospectuses. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered by this prospectus, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or the possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside the United States. See "Underwriting."

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BASIS OF PRESENTATION

As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," the "Company," "Harmony," "Harmony Biosciences" and similar references refer to Harmony Biosciences Holdings, Inc. together with its subsidiary.

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Our fiscal year ends on December 31 of each year. References to fiscal 2019 and 2019 are references to the year ended December 31, 2019. Our most recent fiscal year ended on December 31, 2019.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our consolidated financial statements included elsewhere in this prospectus. Certain other amounts that appear in this prospectus may not sum due to rounding.

TRADEMARKS

This prospectus includes certain trademarks and trade names, including the registered trademark product name "WAKIX," which we have in-licensed from Bioprojet Société Civile de Recherche, or Bioprojet, for use in the United States, and the registered trademark "KNOW NARCOLEPSY," as well as our brand and logo "HB," "HB HARMONY BIOSCIENCES" and "HARMONY BIOSCIENCES," which are protected under applicable intellectual property laws. We also have trademark applications pending with the U.S. Patent and Trademark Office for "REM AT THE WRONG TIME" and "NON-REM AT THE WRONG TIME." This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including the "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Some of the statements in this prospectus constitute forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients with rare neurological disorders living with unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action, or MOA, specifically designed to increase histamine signaling in the brain by binding to H3 receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of our lead indication, excessive daytime sleepiness, or EDS, in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance. We plan to pursue label expansion for WAKIX in narcolepsy in pediatric patients and engage with the FDA in pursuit of pediatric exclusivity. We currently expect to initiate a Phase 3 clinical trial in pediatric patients in the second half of 2021 in pursuit of indications for both EDS and cataplexy. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication for WAKIX. We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through H₃ receptors and histamine signaling. We are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome, or PWS, and myotonic dystrophy, or MD. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020, with topline results expected in the first half of 2022. We are also planning to commence a Phase 2 clinical trial in adult patients with MD in the first half of 2021, with topline results expected in the second half of 2022, subject to receiving authorization to proceed under an Investigational New Drug application, or IND. Beyond these indications, we intend to further explore pitolisant in other rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.

Narcolepsy is a rare, chronic and debilitating neurologic disorder of sleep-wake state instability that is estimated to affect approximately 165,000 Americans, with fewer than 50% diagnosed. Narcolepsy is characterized by EDS, which is present in all patients with narcolepsy and is the primary reason why patients seek treatment. EDS is the inability to stay awake or alert throughout the day, including an irrepressible need for sleep, with lapses into drowsiness or sleep, which has a significant impact on a patient's ability to function. Additional symptoms of narcolepsy may include cataplexy (which is characterized by sudden and transient episodes of muscle weakness accompanied by full conscious awareness), hallucinations, sleep paralysis and disrupted nighttime sleep. In most patients, narcolepsy is caused by the loss of hypocretin, a neuropeptide in the brain that, along with histamine, works to support sleep-wake state stability. The U.S. narcolepsy market had an approximate net sales value of \$1.8 billion in 2019, which is expected to grow due to the addition of newly approved therapies, increased physician education and patient awareness, and increased diagnosis rates, among other factors.

Prior to the approval of WAKIX, there were six approved medications to treat patients with narcolepsy, all of which are scheduled as controlled substances. These include Xyrem (sodium oxybate), Provigil (modafinil), Nuvigil (armodafinil), Ritalin (methylphenidate), Adderall (amphetamine salts) and Sunosi (solriamfetol). These approved drugs are prescribed in accordance with their individual labels for indications covering narcolepsy, cataplexy and/or EDS related to narcolepsy, and have demonstrated the ability to improve the lives of the patients suffering from these indications. Other prescription drugs are used off-label for the treatment of either EDS or cataplexy in patients with narcolepsy, including stimulants for EDS and antidepressants for cataplexy. Despite the benefits provided by the available medications, according to the American Academy of Sleep Medicine, traditional stimulants, wakepromoting agents and sodium oxybate, at best, provide only moderate improvement in narcolepsy symptoms and side effects may limit their use. Some of the current therapies have significant side effects (such as increased heart rate and blood pressure) and boxed warnings due to the risk of respiratory depression, abuse and dependence. These therapies also have the potential for rebound and withdrawal symptoms. The Voice of the Patient report from the FDA's patient-focused drug development initiative, published in 2014, concluded that, based on the overall benefit-risk assessment of current medications, there is a continued need for additional effective and tolerable treatment options for patients with narcolepsy. Similarly, in market research sponsored by us prior to the commercial release of WAKIX, both patients and healthcare professionals, or HCPs, expressed frustration and dissatisfaction with then-existing therapies, reflecting current unmet medical needs. These unmet needs included, in order of importance, the availability of: (i) non-scheduled treatment options, (ii) more tolerable treatment regimens, (iii) more effective treatment options, (iv) novel MOAs beyond currently available therapies and (v) once-daily treatment options.

Clinical Development of WAKIX (pitolisant)

The strategy behind the clinical development of pitolisant is based on its MOA. Pitolisant is a first-in-class molecule with a novel MOA, acting as a potent and highly selective antagonist/inverse agonist of the H3 receptor. It activates histaminergic neurons in the brain, a neuronal system involved in the maintenance of wakefulness, attention, vigilance and cognition. Pitolisant binds to H3 receptors on presynaptic neurons and blocks the normal negative feedback mechanism for histamine release, resulting in increased release of this wake-promoting neurotransmitter. It also functions as an inverse agonist, resulting in enhanced histamine synthesis and release from presynaptic neurons. Increased histamine available in the synapse binds to postsynaptic H1 receptors, activating postsynaptic neurons, which stimulate wake-promoting brain regions and inhibit sleep-promoting regions of the brain.

Pitolisant also stimulates the release of other wake-promoting neurotransmitters (dopamine, norepinephrine, serotonin and acetylcholine) via H3 heteroreceptors within those neuronal systems. Importantly, pitolisant does not increase dopamine levels in the striatum, including the nucleus accumbens, which is the brain's reward center, where an increase in dopamine levels is correlated with abuse potential. This feature of pitolisant's MOA, along with primarily working through the histaminergic system, are two of the aspects that differentiate pitolisant from all other currently approved treatments for narcolepsy.

The safety profile of pitolisant is based on pooled safety data from 22 Phase 2/3 clinical trials conducted by our licensor Bioprojet Société Civile de Recherche, or Bioprojet, eight of which were in patients with narcolepsy and 14 of which were in other indications. These trials included a total of 1,513 unique patients, of whom 1,043 received pitolisant in double-blind, placebo-controlled studies, and others received pitolisant in single-blind or open-label trials. Three successful pivotal trials in narcolepsy, HARMONY 1, HARMONY 1bis, and HARMONY CTP, were completed in Europe by Bioprojet and served as the foundation for the approval of pitolisant by the European Medicines Agency, or EMA, in 2016 for the

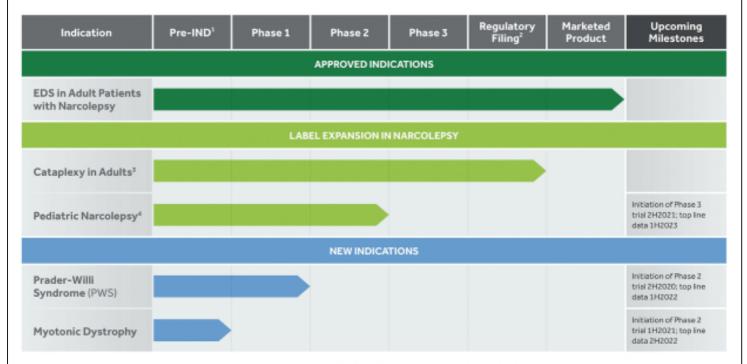
treatment of narcolepsy in adults with or without cataplexy. Pitolisant was evaluated in a long-term safety and tolerability trial, HARMONY 3, which further supported the results observed in HARMONY 1, HARMONY 1bis, and HARMONY CTP. We submitted the data from these same trials, along with a human abuse potential, or HAP, trial, to the FDA as part of the NDA for WAKIX (pitolisant), which the FDA approved on August 14, 2019 for the treatment of EDS in adult patients with narcolepsy.

WAKIX for Narcolepsy

WAKIX (pitolisant) represents a novel approach to narcolepsy treatment. We believe that WAKIX offers a meaningfully differentiated product profile over current treatment options for the following reasons:

- *First-in-class molecule with a novel MOA*. WAKIX is the only selective H₃ receptor antagonist/inverse agonist approved by the FDA for the treatment of EDS in adult patients with narcolepsy and is the only narcolepsy treatment that works primarily through histamine. a major wake-promoting neurotransmitter.
- First-and-only non-scheduled treatment for narcolepsy. WAKIX is the first-and-only FDA-approved treatment for narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration, or the DEA. In a clinical trial, pitolisant demonstrated statistically significantly lower drug liking compared to phentermine (a Schedule IV stimulant), consistent with its lack of abuse potential.
- WAKIX is not a stimulant. Unlike stimulants, WAKIX has shown no evidence for the development of drug tolerance or withdrawal symptoms. Therefore, there is no need for patients to temporarily stop the medication to reset efficacy. In addition, unlike stimulants, WAKIX does not increase dopamine levels in the brain's reward center, which contributes to its lack of abuse potential.
- WAKIX can be used as monotherapy or administered concomitantly with other narcolepsy treatments. Narcolepsy is
 a difficult disorder to manage and the majority of narcolepsy patients often require multiple medications to treat their
 symptoms. WAKIX was studied in combination with each of modafinil and sodium oxybate (two common treatments for
 narcolepsy) and demonstrated no effect on the pharmacokinetic, or PK, profile of either treatment, and neither treatment had
 a clinically relevant effect on the PK profile of WAKIX.
- WAKIX is a once-daily oral tablet administered in the morning upon wakening. Patients have identified a need for
 treatment options that are easier to take and are dosed less frequently. We believe that once-daily dosing with WAKIX
 addresses this need and may help improve patient compliance with treatment.





- For each potential new indication, we do not anticipate being required to conduct additional preclinical studies or studies enabling an IND
 beyond those studies that are already included in the New Drug Application for WAKDX. Additional preclinical studies were not required to open the IND for PWS.
- 2. Includes New Drug Applications and supplemental New Drug Applications.
- 3. We received a Complete Response Letter for cataplexy in August 2019; the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We are evaluating our options regarding the approach to take in pursuit of this indication.
- Current trial being conducted by Bioprojet. We plan to initiate a Phase 3 clinical trial in 2H2021 in pursuit of pediatric indications for both EDS and catapiexy as well as pediatric exclusivity.

Potential New Indications for Pitolisant

Label Expansion

We are actively working on label expansion for WAKIX in narcolepsy, including label expansion for the treatment of pediatric patients suffering from narcolepsy. Approximately 3,600 of the diagnosed narcolepsy patients in the United States are pediatric patients 19 years of age or under. We believe that these pediatric patients could benefit from new treatment options. Accordingly, we currently expect to initiate a Phase 3 clinical trial in the second half of 2021 for indications for both EDS and cataplexy in pediatric patients. Topline results from this clinical trial are expected in the first half of 2023. We also intend to work with the FDA toward obtaining pediatric exclusivity for WAKIX.

In addition, the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We are evaluating our options regarding the approach to take with the FDA to expand the label for WAKIX for cataplexy in adults despite the initial FDA decision not to approve WAKIX for cataplexy. While all patients with narcolepsy have the primary symptom of EDS, it is estimated that 60% to 70% of those diagnosed with, and treated for, narcolepsy also experience cataplexy, representing approximately 25,000 to 30,000 patients in the United States. We believe that an additional indication for cataplexy in adult patients would strengthen the product profile for WAKIX and enable access to WAKIX for adult patients suffering from both EDS and cataplexy associated with narcolepsy. Depending on the regulatory path we pursue for approval, we could obtain the adult cataplexy indication as early as the second half of 2020, if ever. If we conduct an additional clinical trial to gain a cataplexy indication in adult patients with narcolepsy, we anticipate that any such clinical trial will be funded by Bioprojet pursuant to our License and Commercialization Agreement with Bioprojet,

or the Bioprojet License Agreement. If we are granted approval for a cataplexy indication with or without the need for an additional trial, we will need to make a milestone payment to Bioprojet in accordance with the Bioprojet License Agreement. If that outcome should occur, we may use a portion of the proceeds of this offering to fund such milestone payment. See "Use of Proceeds" and "Business—Strategic Agreement—License and Commercialization Agreement with Bioprojet."

Additional Indications

We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through the H3 receptor and histamine signaling. We plan to explore the potential benefit of pitolisant in additional rare neurological indications beyond narcolepsy, initially focusing on the treatment of EDS associated with PWS and MD. For these potential new indications, we do not anticipate being required to conduct additional preclinical studies or studies enabling an IND beyond those studies that are already included in the NDA for WAKIX, which were cross-referenced in the IND submission for PWS. Similarly, we intend to reference these studies when the IND for MD is submitted.

PWS is a rare genetic disorder caused by a loss of function of specific genes on chromosome 15 resulting in hypothalamic dysfunction. The hypothalamus controls both sleep-wake states and hunger-satiety. Therefore, two of the main symptoms in patients with PWS are EDS and insatiable hunger, or hyperphagia. It is estimated that approximately 15,000 to 20,000 people in the United States suffer from PWS, and over half of those suffering from PWS also have reported or experienced EDS. We submitted an IND in October 2019 and received acknowledgement from the FDA that the proposed clinical investigation may proceed. We subsequently completed a Phase 1 PK clinical trial in pediatric patients with PWS in the fourth quarter of 2019, and initiated a long-term, open-label safety trial in these patients. We intend to commence a Phase 2 clinical trial in patients with PWS in the second half of 2020. Topline results from this clinical trial are expected in the first half of 2022.

MD is a rare, multi-system genetic disease that affects the neuromuscular system as well as several other systems. It is inherited in an autosomal dominant pattern and there are two main types: type 1, or DM1, and type 2, or DM2. The underlying cause of DM1 is a mutation in the myotonic dystrophy protein kinase gene on chromosome 19. DM1 is the most common form of adult-onset muscular dystrophy and affects as many as 140,000 patients in the United States. EDS and fatigue are hallmark clinical characteristics in the majority of patients with DM1 and are referred to as the most frequent non-muscular symptoms in patients with DM1. Cognitive impairment is also a prominent symptom in patients with DM1 and all of these symptoms are thought to be mediated through H3 receptors and histaminergic pathways located throughout the central nervous system, or CNS. DM2 is not as common as DM1 with an estimated prevalence of between 3,000 and 29,000 patients in the United States. The underlying cause of DM2 is a mutation in the CCHC-Type Zinc Finger Nucleic Acid Binding Protein gene on chromosome 3. Patients with DM1 and DM2 share similar phenotypes but disease onset is later in patients with DM2 and symptoms tend to be milder. A pre-IND meeting was scheduled with the FDA for March 2020 to discuss a trial in DM1 patients, but was cancelled because we deemed the preliminary meeting comments adequate to advance the program forward. We are now planning to include both patients with DM1 and patients with DM2 in our trial, subject to feedback from the FDA and receiving authorization to proceed under an IND, and we anticipate commencing a Phase 2 clinical trial in adult patients with MD in the first half of 2021. Topline results from this clinical trial are expected in the second half of 2022.

Our Strategy

Our goal is to become a leading pharmaceutical company dedicated to developing and commercializing novel treatment options for patients with rare neurological disorders living with unmet medical needs, beginning with a focus on narcolepsy. The key elements of our strategy are to:

- Commercialize WAKIX in the United States. We have assembled a team of approximately 150 professionals that possess comprehensive life sciences experience. We have also established a robust company infrastructure to execute on our core business and growth strategies. This team includes over 70 dedicated and experienced sales professionals who call on the approximately 8,000 HCPs who treat approximately 90% of narcolepsy patients in the United States. In November 2019, we launched commercial sales of WAKIX in the United States.
- Expand WAKIX Label in Narcolepsy. Building upon an EDS indication in adult patients with narcolepsy, we expect to initiate a Phase 3 clinical trial in pediatric narcolepsy patients in the second half of 2021 with the goal of gaining a pediatric indication for both EDS and cataplexy. We also plan to engage with the FDA to pursue pediatric exclusivity. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication.
- Pursue New Indications Beyond Narcolepsy. We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through the H3 receptor and histamine signaling. We plan to explore the potential benefit of pitolisant in additional rare neurological indications beyond narcolepsy, initially focusing on the treatment of EDS associated with PWS and MD. Beyond these indications, we intend to further explore pitolisant in other rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.
- Explore Expansion of our Product Portfolio. We plan to explore obtaining additional licensing rights from Bioprojet to expand into certain international markets with WAKIX. As we continue our commercial growth and develop a global footprint, we will assess in-licensing or acquiring complementary rights, assets or product candidates that allow us to leverage our existing infrastructure and expand within our strategic areas of focus.

Early Launch Metrics

As of May 31, 2020, over 1,600 unique HCPs (out of a total of approximately 8,000 HCPs who treat approximately 90% of diagnosed narcolepsy patients) have prescribed WAKIX since it became available in November 2019 to a total of over 2,400 unique patients (out of the approximately 42,000 diagnosed and treated narcolepsy patients in the United States). We have secured formulary access for over 161 million lives, which represents 68% of our target covered lives, which we define as a group of certain public and private payors that account for approximately 80% of all covered lives in the United States. Over 2,400 patients have started on WAKIX. For the three months ended March 31, 2020, net sales of WAKIX were \$19.8 million.

Company History and Management Team

Our operating subsidiary, Harmony Biosciences, LLC, was formed in May 2017. We were formed in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and we converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017. We concurrently acquired an exclusive license to develop, manufacture and commercialize pitolisant in the United States from

Bioprojet. In February 2020, we changed our name to Harmony Biosciences Holdings, Inc. Since founding, we have assembled an experienced leadership team with a track record of developing and commercializing products to treat rare neurological disorders. Our President and Chief Executive Officer is John Jacobs, who has held a variety of senior leadership roles of increasing responsibility throughout his career including roles in marketing, commercial, operations and general management in both U.S. and global markets. Jeffrey Dierks, our Chief Commercial Officer, has over 20 years of commercial leadership experience with demonstrated success in leading product launches. Jeffrey Dayno, MD, our Chief Medical Officer, is a neurologist with 10 years of experience in clinical and academic medicine followed by over 20 years of experience in research and development leadership roles at Merck & Co., Inc., Cephalon, Inc. and ViroPharma Incorporated.

Summary Risk Factors

Investing in our common stock involves substantial risk. Our ability to execute our strategy is also subject to certain risks. The risks described under the heading "Risk Factors" included elsewhere in this prospectus may cause us not to realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the most significant challenges and risks include the following:

- We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have only generated limited revenue from product sales and may never be profitable.
- We have a limited operating history and no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have only limited capital and, even if we consummate this offering, may need to raise additional capital before we become profitable.
- Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.
- · Our management has expressed substantial doubt about our ability to continue as a going concern.
- We may be required to make significant payments to Bioprojet under our licensing and collaboration agreements for pitolisant.
- We are substantially dependent on our ability to successfully commercialize WAKIX, which is currently our only approved
 product. If we are unable to successfully commercialize WAKIX, our ability to generate revenue and our financial condition
 will be adversely affected.
- The commercial adoption of WAKIX and any other product candidates we develop will depend on the degree of their market acceptance.
- We rely on our license agreement with Bioprojet to provide rights to the core intellectual property relating to pitolisant, and any termination or loss of significant rights under the agreement would adversely affect our development and/or commercialization of pitolisant.
- Our business is subject to risks arising from epidemic diseases, such as the recent outbreak of the COVID-19 pandemic.

- Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in science in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.
- The regulatory approval process of the FDA is costly, lengthy and inherently unpredictable, and if we are ultimately unable to
 obtain regulatory approval for pitolisant in other potential indications for which we may seek to develop pitolisant, our
 business will be substantially harmed.
- If we fail to obtain and sustain an adequate level of coverage and reimbursement for WAKIX and other product candidates by third-party payors, sales would be adversely affected.
- WAKIX has been approved by the FDA for the treatment of EDS in adult patients with narcolepsy. Regulatory approval is
 limited by the FDA to the specific indication for which approval has been granted and, unless we seek regulatory approval for
 additional indications, we will be prohibited from marketing pitolisant for other indications. We may be subject to fines,
 penalties or injunctions if we are determined to have promoted or be promoting the use of pitolisant for unapproved or
 "off-label" uses, resulting in damage to our reputation and business.

Our Corporate Information

Our corporate headquarters are located at 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania 19462. Our telephone number is (484) 539-9800. Our principal website address is *www.harmonybiosciences.com*. The information on or accessed through our website is not incorporated in this prospectus or the registration statement of which this prospectus forms a part.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of certain reduced reporting and other requirements that are otherwise generally applicable to public companies. As a result:

- we are required to present only two years of audited financial statements and two years of related selected financial data and Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- we are not required to engage an auditor to report on our internal control over financial reporting pursuant to Section 404(b)
 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or the PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., critical audit matters);
- we are not required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay,"
 "say-on-frequency" and "say-on-golden parachutes;" and
- we are not required to comply with certain disclosure requirements related to executive compensation, such as the
 requirement to disclose the correlation between executive compensation and performance and the requirement to present a
 comparison of our Chief Executive Officer's compensation to our median employee compensation.

We may take advantage of these reduced reporting and other requirements until the last day of our fiscal year following the fifth anniversary of the completion of this offering, or such earlier time that we are no longer an emerging growth company. However, if certain events occur prior to the end of such five-year period, including if we have more than \$1.07 billion in annual gross revenue, have more than \$700 million in market value of our common stock held by non-affiliates, or issue more than \$1.0 billion of non-convertible debt over a three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We may choose to take advantage of some but not all of these reduced burdens. We have elected to adopt the reduced requirements with respect to our financial statements and the related selected financial data and Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure. As a result, the information that we provide to stockholders may be different from the information you may receive from other public companies in which you hold equity.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the longer phase-in periods for the adoption of new or revised financial accounting standards under the JOBS Act until we are no longer an emerging growth company. Our election to use the phase-in periods permitted by this election may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the longer phase-in periods permitted under the JOBS Act and who will comply with new or revised financial accounting standards. If we were to subsequently elect instead to comply with public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We are also a "smaller reporting company" as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates on the last business day of our second fiscal quarter is less than \$250.0 million, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and nonvoting common stock held by non-affiliates on the last business day of our second fiscal quarter in that fiscal year is less than \$700.0 million.

THE OFFERING

Common stock offered by us

Option to purchase additional shares

Common stock to be outstanding after this offering

Use of proceeds

Risk factors

Dividend policy

shares.

shares.

shares (or shares if the underwriters exercise their option to purchase additional shares in full).

We estimate, based upon an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus), that we will receive net proceeds from this offering of approximately \$ million (or \$ million if the underwriters exercise their option to purchase additional shares of common stock in full), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently estimate that we will use the net proceeds from this offering to fund the clinical development of additional indications for pitolisant in PWS, MD and pediatric narcolepsy, and for working capital, business development opportunities, a potential milestone payment to Bioprojet and general corporate purposes, including to support the continued commercialization of WAKIX in the United States. See "Use of Proceeds."

See "Risk Factors" beginning on page 15 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The terms of our current certificate of incorporation provide that, upon the conversion of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock into shares of our common stock upon the closing of this offering, each holder of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock will receive a cumulative accrued dividend calculated at a rate per annum of 10% of the applicable issue price of such series of preferred stock, in each case, compounded annually, payable, at the determination of our board of directors, in either (i) shares of common stock or (ii) cash in an aggregate amount equal to the cumulative accrued dividend. We intend to pay the

cumulative accrued dividend in shares of common stock. Assuming we pay the cumulative accrued dividend in shares of common stock, the cumulative accrued dividend will be issued to each holder of preferred stock as of immediately prior to the closing of this offering a number of shares of common stock equal to (x) the aggregate amount of the accrued dividend held by such holder and not previously paid as of immediately prior to the closing of this offering divided by (y) the actual price per share of common stock sold to the public in this offering. Based on the midpoint of the price range set forth on the cover page of this prospectus, we expect to issue (i) shares of our common stock for cumulative accrued dividends to holders of our Series A preferred stock, (ii) shares of our common stock for cumulative accrued dividends to holders of our Series B preferred stock and (iii) shares of our common stock to holders of our Series C preferred stock. The stock dividends will not be paid on any shares of our common stock purchased in this offering. We do not pay dividends on our common stock and do not anticipate paying any dividends on our common stock for the foreseeable future. Any future determinations relating to our dividend policy will be made at the discretion of our board of directors and will depend on various factors. See "Dividend Policy."

Proposed Nasdaq Market symbol

The number of shares of common stock to be outstanding after this offering is based on shares of our common stock outstanding as of March 31, 2020, and includes an additional shares of our common stock issuable upon (i) the conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering into shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock which becomes due and payable to such holders upon the conversion of their convertible preferred stock upon the closing of this offering, and excludes:

shares of common stock issuable upon exercise of outstanding stock options granted under the Harmony
Biosciences II, Inc. Equity Incentive Plan, or the Equity Incentive Plan, as of March 31, 2020, at a weighted average exercise
price of \$ per share;

"HRMY"

- shares of common stock available for future issuance under the Equity Incentive Plan as of March 31, 2020; and
- shares of our common stock that will become available for future issuance under our 2020 Incentive Award Plan, or the 2020 Plan, which will become effective in connection with the completion of this offering.

Unless we indicate otherwise or the context otherwise requires, all information in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the conversion of all outstanding shares of our Series A preferred stock, Series B preferred stock and Series C preferred stock into shares of our common stock immediately prior to the closing of this offering;
- the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of of our common stock;
- a for split of our common stock, effected on , 2020;
- no exercise of the outstanding options described above after March 31, 2020;
- no exercise by the underwriters of their option to purchase up to
 additional shares of common stock; and
- an initial public offering price of \$ per share of common stock, which is the midpoint of the range set forth on the cover page of this prospectus.

Summary Consolidated Financial Data

The following tables present our summary consolidated financial data. We have derived the summary consolidated statements of operations data for the three months ended March 31, 2020 and 2019 and the summary consolidated balance sheet data as of March 31, 2020 from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations data for the year ended December 31, 2019 and 2018 and the summary consolidated balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited interim condensed consolidated financial statements on a basis substantially consistent with our audited consolidated financial statements as of and for the year ended December 31, 2019, and the unaudited interim condensed consolidated financial statements include all normal recurring adjustments necessary for a fair statement of the financial information set forth in those unaudited interim condensed consolidated financial statements. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results, and our operating results for the three-month period ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 or any other interim periods or any future year or period.

Consolidated Statement of Operations Data: (U.S. dollars in thousands except share and per share data)		ree Months Ended March 31, 2020		ee Months Ended larch 31, 2019	-	ear Ended cember 31, 2019	Dec	ar Ended ember 31, 2018
Net product revenue	\$	19,840	\$	_	\$	5,995	\$	_
Cost of product sales		3,474		_		1,577		
Gross profit		16,366		_		4,418		_
Operating expenses:								
Research and development	\$	3,431	\$	52,990	\$	69,595	\$	12,372
Sales and marketing		13,254		6,191		44,318		16,861
General and administrative		9,290		3,962		36,409		12,206
Total operating expenses		25,975		63,143		150,322		41,439
Operating loss		(9,609)		(63,143)		(145,904)		(41,439)
Loss on debt extinguishment		(22,639)		_		_		
Interest income (expense)		(6,372)		122		(6,073)		1,541
Loss before taxes		(38,620)		(63,021)		(151,977)		(39,898)
Income taxes		_		_		_		_
Net loss and comprehensive loss	\$	(38,620)	\$	(63,021)	\$	(151,977)	\$	(39,898)
Accumulation of yield on preferred stock		(10,445)		(8,314)		(35,231)		(30,185)
Net loss available to common stockholders	\$	(49,065)	\$	(71,335)	\$	(187,208)	\$	(70,083)
Loss per share:								
Loss per share, basic and diluted(1)(2)	\$	(0.77)	\$	(1.12)	\$	(2.93)	\$	(0.96)
Weighted average number of common stock, basic and diluted	64	4,000,341	63	3,888,876	6	3,891,677	72	2,765,366
Pro Forma net loss per share, basic and diluted (unaudited)(1)(2)	\$	_	\$	_	\$	_	\$	_
Pro Forma weighted average shares of common stock outstanding, basic and diluted (unaudited)								

- (1) See Note 13 to our financial statements for the three months ended March 31, 2020 appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.
- (2) See Note 15 to our financial statements for the year ended December 31, 2019 appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	As of March 31, 2020					
Consolidated Balance Sheet Data:			Pro Forma			
(U.S. dollars in thousands except share and per share data)	Actual	Pro Forma(2)	As Adjusted(3)			
Cash and cash equivalents	\$ 71,517					
Working capital(1)	74,048					
Total assets	163,094					
Warrant liability	3,505					
Long-term debt, net	192,177					
Convertible preferred stock	422,643					
Total stockholders' (deficit) equity	(472,330)					

- (1) We define working capital as current assets less current liabilities.
- The pro forma balance sheet data give effect (i) the conversion of all outstanding shares of our convertible preferred immediately prior to the closing of this offering into shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock which becomes due and payable to such holders upon the conversion of their convertible preferred stock upon the closing of this offering.
- (3) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have only recently begun to generate revenue from product sales and have incurred losses in each year since our inception. Our ability to generate revenue and achieve profitability depends on our ability to successfully commercialize WAKIX for the treatment of excessive daytime sleepiness, or EDS, in adult patients with narcolepsy, and to successfully develop and obtain the regulatory approvals necessary to commercialize pitolisant for other indications. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we commercialize WAKIX and as we continue to develop and potentially commercialize pitolisant for other indications.

We have only generated limited revenue from product sales and may never be profitable.

Other than WAKIX, we do not currently have any products that are available for commercial sale, and we may never achieve profitability. Our net loss was \$38.6 million and \$63.0 million for the three months ended March 31, 2020 and 2019, respectively, and our net loss was \$152.0 million and \$39.9 million for the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, we had an accumulated deficit of \$472.3 million. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue until we further commercialize WAKIX and obtain regulatory approval for potential additional indications for pitolisant, or any other product candidates we may develop. We generated net product revenues of \$19.8 million and zero for the three months ended March 31, 2020 and 2019 net product revenues of \$6.0 million and zero for the years ended December 31, 2019 and 2018, respectively. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval, including marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or

continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have a limited operating history and no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2017, and our operations to date have been largely focused on staffing our company, business planning, raising capital, acquiring the rights to pitolisant, seeking registration in the United States for our product WAKIX, which is approved for the treatment of EDS in adult patients with narcolepsy, commercialization efforts associated with WAKIX and preparing to develop pitolisant for other potential indications. This has included preparing the application for regulatory approval and other activities that were required for us to obtain approval of our New Drug Application, or NDA, and activities related to preparing for the commercialization of WAKIX. WAKIX is our only drug candidate for which we have obtained regulatory approval. We have not yet demonstrated our ability to successfully manufacture a drug on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We need to continue to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors, and may not be successful in such a transition.

We have only limited capital and, even if we consummate this offering, may need to raise additional capital before we become profitable.

As of March 31, 2020, we had an accumulated deficit of \$472.3 million, and available cash and cash equivalents of \$71.5 million. We have \$200.0 million of debt outstanding under our credit agreement, or the Credit Agreement, with OrbiMed Royalty & Credit Opportunities III, LP, or OrbiMed. We believe that our existing cash as of March 31, 2020 and the estimated net proceeds from this offering will be sufficient to meet our anticipated cash requirements through at least December 31, 2021. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Because the length of time and activities associated with the successful development of our product candidates is highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities.

To fund future operations to the point at which we are able to generate positive cash flow from sales of WAKIX or other potential product candidates, we may need to raise significant additional capital. The amount and timing of future funding requirements will depend on many factors, including, but not limited to:

- · the progress and results of our commercialization of WAKIX;
- the effect of competing technological and market developments:
- · the cost and timing of commercial-scale manufacturing activities;
- the payment of licensing fees to Bioprojet Société Civile de Recherche, or Bioprojet;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other regulatory authorities;

- the willingness of the FDA and other comparable regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for the review and approval of pitolisant for other potential indications or of any other product candidates;
- the potential expansion of our current development programs to seek new indications for pitolisant, potential new development programs for additional indications, and related general and administrative support;
- the initiation, progress, timing, and results of our clinical trials through all phases of development for pitolisant as a treatment for other indications and any other product candidates;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, in-licensed or otherwise;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us for pitolisant or future product candidates;
- the cost of acquiring rights to other pharmaceutical products in the future to further develop and commercialize;
- · the cost of general operating expenses;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where those product candidates are approved and where we choose to commercialize our products on our own; and
- · the costs of operating as a public company.

Other than our Credit Agreement with OrbiMed, we have no committed source of additional capital and we anticipate that we may seek to fund our operations through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. Although we have been successful in obtaining financing through the issuance of our equity securities and debt facilities, we cannot assure you that we will be able to do so in the future. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us to fund our commercialization of WAKIX and clinical development and commercialization of pitolisant for other indications, if approved, and other business activities, we could be forced to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or curtail or cease our operations.

Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate sufficient product revenue from the sale of WAKIX, we may need to finance our cash needs through a combination of equity offerings, debt financings, including our Credit Agreement, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as

incurring additional debt, making capital expenditures or declaring dividends, which could adversely affect our ability to conduct our business

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Our management has expressed substantial doubt about our ability to continue as a going concern.

The consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred operating losses and negative cash flows from operations since inception. As of March 31, 2020, we had an accumulated deficit of \$472.3 million. Management expects to continue to incur operating losses and negative cash flows from operations in 2020. In addition, we are subject to two further milestone payments pursuant to our license agreement with Bioprojet: (i) a milestone payment of \$40.0 million upon the attainment of aggregate net sales of WAKIX in the United States of \$500.0 million subsequent to the date of NDA approval by the FDA and (ii) a milestone payment of \$102.0 million if we receive NDA approval from the FDA for a cataplexy indication. We have financed our operations to date with proceeds from the sale of preferred securities and drawing down on (i) a loan agreement with CRG Servicing LLC that has since been repaid in full and (ii) our Credit Agreement.

If we are unable to successfully complete this offering, we will need to create alternate financing or operational plans to continue as a going concern. There can be no assurance that such alternate financing, if available, can be obtained on acceptable terms. If we are unable to obtain such alternate financing, future operations would need to be scaled back or discontinued.

Accordingly, these factors raise substantial doubt about our ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We may be required to make significant payments to Bioprojet under our licensing and collaboration agreements for pitolisant.

Under our agreements with Bioprojet, we are subject to significant obligations, including payment obligations upon the achievement of specified milestones and payments based on product sales, as well as other material obligations. Certain of the milestone payments payable by us under these agreements were paid prior to our commercialization of WAKIX. We may be required to make additional milestone payments of up to \$142.0 million in the future prior to the time at which we are able to generate significant revenue from sales of WAKIX. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. If we fail to comply with our payment obligations, Bioprojet may have the right to terminate the license agreement, in which event we would not be able to develop, manufacture or market WAKIX or any other pitolisant-based product candidate. Furthermore, if we are forced to raise additional funds to make such payments, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards of approximately \$147.8 million and \$139.3 million, respectively. Our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if we experience an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in the ownership of our equity by certain stockholders over a rolling three-year period. Similar provisions of state tax law may also apply to limit the use of our state net operating loss carryforwards. We have not assessed whether such an ownership change has previously occurred. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing net operating loss carryforwards to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Section 382 of the Code. As a result, if or when we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

Our credit agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our Credit Agreement with OrbiMed contains certain restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event that, we engage in new lines of business, incur additional indebtedness or liens, make certain investments, make certain payments, pay cash dividends, merge with other companies or consummate certain changes of control, acquire other companies, transfer or dispose of certain assets, liquidate or dissolve, amend certain material agreements, enter into sale and leaseback transactions, enter into various other specified transactions, or change our name, location, executive office or executive management without notice. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of OrbiMed or prepay the outstanding amount under the Credit Agreement. The Credit Agreement also contains certain financial covenants, including minimum revenue and cash balance requirements (which include maintaining minimum liquidity of \$12.5 million), and financial reporting requirements. Our obligations under the Credit Agreement are secured by all of our property, with certain exceptions. We may not be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the Credit Agreement. Furthermore, our future working capital, borrowings or equity financing could be unavailable to repay or refinance the amounts outstanding under the Credit Agreement. In the event of a liquidation, OrbiMed would be repaid all outstanding principal and interest prior to distribution of assets to unsecured creditors, and the holders of our common stock would receive a portion of any liquidation proceeds only if all of our creditors then existing, including OrbiMed, were first repaid in full.

Risks Related to Our Business

We are substantially dependent on our ability to successfully commercialize WAKIX, which is currently our only approved product. If we are unable to successfully commercialize WAKIX, our ability to generate revenue and our financial condition will be adversely affected.

Since our inception, we have invested substantially all of our capital resources on the development, registration and commercialization of WAKIX, which was approved for the treatment of EDS in adult patients with narcolepsy in August 2019. We cannot be certain that WAKIX will be successfully commercialized.

Our ability to generate revenue from product sales depends heavily on our success in many areas, including but not limited to:

successfully commercializing WAKIX, either independently or with marketing service providers;

- the effectiveness of our sales and marketing strategy and operations, and obtaining market acceptance of WAKIX, including garnering market share from existing and future treatment alternatives;
- maintaining compliance with all regulatory requirements applicable to WAKIX and our commercial activities, including the postmarketing requirements and post-marketing commitments required by the FDA;
- · obtaining coverage and adequate reimbursement from third-party payors for each of our product candidates;
- the continued acceptability of the safety profile of WAKIX and the occurrence of any unexpected side effects, adverse reactions
 or misuse, including potential business impact such as the need to withdraw the product (either voluntarily or as mandated by the
 FDA), loss of support by the advocacy communities or loss of positive corporate reputation resulting in related unfavorable media
 coverage in these areas;
- · successfully managing third-party service providers involved in the manufacturing and development of pitolisant;
- successfully completing the development of pitolisant in other indications by demonstrating safety, tolerability and efficacy profiles that are satisfactory to the FDA;
- obtaining regulatory approvals to market pitolisant for other indications;
- · complying with the terms of the license agreement with Bioprojet;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding the portfolio of intellectual property rights, including patents, trade secrets and knowhow;
 and
- · attracting, hiring and retaining qualified personnel.

In our efforts to market WAKIX for the treatment of EDS in adult patients with narcolepsy, our revenue will be dependent, in part, on the size of the markets in the United States, or in other territories where we may seek and obtain regulatory approval, the number of competitors in such markets, the acceptance of the price of the product in those markets and the ability to obtain reimbursement at any price. If the number of our addressable patients is not as large as we estimate or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products. If we are not able to generate substantial revenue from the sale of approved products, we may never become profitable.

The commercial adoption of WAKIX and any other product candidates we develop will depend on the degree of their market acceptance.

Even with the requisite approvals from the FDA and other regulatory authorities, the commercial adoption of WAKIX for the treatment of EDS in adult patients with narcolepsy, and any other indications and product candidates we may develop, will depend on the degree of their acceptance by physicians, patients, third-party payors and others in the medical community. If WAKIX or any other product candidates we develop do not achieve an adequate level of market acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of WAKIX or any other product candidates we develop, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

• the safety and efficacy of the product as demonstrated in clinical trials;

- the perception of physicians, patients, third-party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality-of-life and cost-effectiveness of the product, compared to those of other available treatments;
- the product's approved labeling, including the description of the product's approved indications, the description of its efficacy, including the endpoints in which it showed an improvement, and the prevalence and severity of any side effects, including any associated limitations or warnings;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- · our ability to differentiate WAKIX or other approved products from other treatments in the same space;
- the adoption of WAKIX as a first-line therapy for EDS in adult patients with narcolepsy;
- the prevalence and severity of any side effects, including those that may be discovered following approval and commercialization;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- · the strength of marketing and distribution support and timing of market introduction of competitive products;
- · the publicity concerning our products or competing products and treatments;
- product liability litigation alleging injuries relating to our products or similar classes of drugs;
- any post-approval study requirements for our products and the results thereof; and
- · sufficient third-party insurance coverage and reimbursement.

Our continuing efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits and risks of WAKIX may require significant resources and may never be successful. The adoption of WAKIX could be limited if physicians prescribe it only as a second line therapy. Physicians may opt to prescribe the products of our competitors for a variety of reasons. For example, WAKIX did not demonstrate non-inferiority to modafinil and, as such, physicians and patients may choose modafinil rather than WAKIX. Furthermore, because the clinical response to WAKIX may take several weeks before addressing EDS symptoms, patients and physicians may choose other fast acting, stimulant and wake promoting agents over WAKIX. If WAKIX fails to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

We cannot guarantee that WAKIX or any other product candidates we may seek to develop will ever be commercially successful, and to the extent they are not commercially successful, such product candidates would incur significant expense with no corresponding revenue. Because we expect the sales of WAKIX to generate substantially all of our revenue for the foreseeable future, the failure of WAKIX to find market acceptance would substantially harm our business and could require us to seek additional financing.

The market opportunity for WAKIX or any future product candidate we develop may be smaller than we estimate.

The potential market opportunity for WAKIX and any future product candidate is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include

several key assumptions of the current market size and current pricing for commercially available products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. While we believe our estimates are reasonable and reliable, they may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of diseases and disorders. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for WAKIX or any future product candidate we develop may be limited or may not be amenable to treatment with WAKIX or such future product candidate, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We rely on our license agreement with Bioprojet to provide rights to the core intellectual property relating to pitolisant, and any termination or loss of significant rights under the agreement would adversely affect our development and/or commercialization of pitolisant.

We have licensed our core intellectual property relating to pitolisant from Bioprojet. If, for any reason, our license and commercialization agreement with Bioprojet is terminated or we otherwise lose those rights, it would materially adversely affect our business. Pursuant to our license and commercialization agreement, we obtained intellectual property rights in connection with the commercialization of pitolisant in the United States and its territories, commonwealths and protectorates, including Puerto Rico, which includes an exclusive license to use certain intellectual property owned by Bioprojet related to clinically developing and commercializing the pitolisant product candidate for narcolepsy, obstructive sleep apnea, idiopathic hypersomnia and Parkinson's Disease. Under the license agreement, Bioprojet is responsible for conducting all preclinical studies and clinical trials necessary for achieving and maintaining regulatory approval in the United States for narcolepsy and cataplexy indications, including all costs and expenses. We are responsible for all other costs associated with other development and regulatory activities, unless Bioprojet otherwise agrees to participate in funding such activities. We must obtain consent from Bioprojet before commencing any clinical trials related to pitolisant. Our ability to pursue indications other than the ones specifically enumerated in the license agreement is also contingent on mutual agreement of Bioprojet and us as to those indications and such agreement may be withheld at Bioprojet's discretion. If Bioprojet denies consent for us to conduct clinical trials or pursue any such other indication for any reason, we will not have the right under our license and commercialization agreement to commercialize our product for such indication. In such event, Bioprojet may pursue commercialization of such indication for itself in our territory, or it may license the right to commercialize such indication in our territory to third parties, including our competitors.

Our license and commercialization agreement also imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Bioprojet, and Bioprojet may have the right to terminate our license, which would result in us being unable to develop, manufacture and sell pitolisant and would materially adversely affect our business. See "Business—Strategic Agreement—License and Commercialization Agreement with Bioprojet" for further information.

The outbreak of COVID-19 may result in disruptions to our commercialization, clinical trials, manufacturing and other business operations, which could have a material adverse effect on our business, financial condition, operating results, cash flows and prospects.

The recent outbreak of the Coronavirus Disease 2019, or COVID-19, which has been declared a global pandemic by the World Health Organization, has spread across the globe and is impacting

worldwide economic activity. A public health epidemic, including COVID-19, poses the risk that we or our employees, contractors, suppliers, distributors and other partners, as well as physicians treating narcolepsy patients, may be prevented from conducting business and patient-care activities for an indefinite period of time, including due to shutdowns and quarantines that may be requested or mandated by governmental authorities. Beginning in March 2020, we transitioned our field-based sales, market access, and medical employees to remote work and suspended work-related travel and in-person customer interactions with healthcare professionals and customers. Our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, remote working could increase our cyber security risk. General protective measures put into place at various governmental levels, including quarantines, travel restrictions and business shutdowns, may also negatively affect our operations. The responses to COVID-19 may also have an impact on demand for WAKIX as a result of reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, the reduced ability to see patients due to cancelled appointments and reprioritization of healthcare resources toward COVID-19. Going forward, an impact may potentially be seen on patient compliance and persistence with WAKIX treatment, and the ability to pay for their prescriptions.

The continued spread of COVID-19 and the measures taken by the governments of countries affected, particularly the United States and France, could also disrupt the supply chain and the manufacture or shipment of WAKIX and of drug substance and finished drug product. Any delays or interruptions in the manufacture and supply of WAKIX could result in delays for our planned clinical trials, impair our ability to meet demand for new WAKIX prescriptions and impede our clinical trial recruitment, testing, monitoring, data collection and analysis and other related activities.

Any of the foregoing factors could have a material adverse impact on our business, financial condition, operating results, cash flows and prospects. The extent to which COVID-19 impacts our operations and those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information which emerges concerning the severity of COVID-19 and the actions taken to contain the virus or treat its impact, among others. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, will determine the impact of the pandemic on our operations.

We may not be successful in our efforts to identify, in-license or acquire, discover, develop or commercialize additional product candidates, or identify other indications for pitolisant beyond EDS in adult patients with narcolepsy.

Although a substantial amount of our effort will focus on the commercialization of WAKIX for the treatment of EDS in adult patients with narcolepsy, we also may seek to identify, in-license or acquire, discover, develop and commercialize additional product candidates in the rare neurological disorders field, and to identify other indications for pitolisant beyond EDS in adult patients with narcolepsy. We cannot assure you that our efforts to do so will be successful. Even if we are successful at in-licensing or acquiring additional product candidates, their requisite development activities may require substantial resources, and we cannot assure you that these development activities will result in regulatory approvals. We also cannot assure you that our efforts to develop and commercialize pitolisant for other indications beyond EDS in adult patients with narcolepsy will be successful.

Our business, products or product pricing could be subject to negative publicity, which could have a material adverse effect on our reputation, business, financial position, results of operations, liquidity and cash flows.

In recent years, the pharmaceutical industry has been the subject of public complaints and significant publicity regarding the pricing of pharmaceutical products, including publicity and pressure

resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public has deemed excessive. We may experience downward pricing pressure on the price of WAKIX and any other future approved products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. Orphan drugs in particular have received recent negative publicity for the perceived high prices charged for them by their manufacturers, and as a result orphan drug developers such as us may be negatively impacted by such publicity and any U.S. or other government regulatory response. Due to these factors, we may suffer public criticism and negative publicity in media coverage, by industry trade associations and legislators.

Any of the events or developments described above could result in reputational harm and reduced market acceptance and demand for our products, could harm our ability to market our products in the future, could cause us to incur significant expense, could cause our senior management to be distracted from execution of our business strategy, and could have a material adverse effect on our business, reputation, financial condition, results of operations, liquidity, cash flows and/or share price.

Third-party relationships are important to our business. If we are unable to enter into and maintain strategic collaborations or if these relationships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for manufacturing or distribution. In addition, we may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Relationships we enter into may pose a number of risks, including the following:

- current or future third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- · third parties may not perform their obligations as expected;
- third parties may not pursue development and commercialization of any product candidates that we decide to develop as drugs and that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical study or trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- third parties may delay preclinical studies or clinical trials, provide insufficient funding for a preclinical study or clinical trial, stop a
 preclinical study or clinical trial or abandon one of our product candidates, repeat or conduct clinical studies or new clinical trials
 or require a new formulation of a product candidate for clinical testing;
- third parties could independently develop, or develop with other third parties, products that compete directly or indirectly with our products and product candidates if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our current or future collaborators as competitive with their own product candidates or products, which may cause

such third parties to cease to devote resources to the commercialization of our product candidates;

- third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, packaging, labeling, holding, distribution and/or marketing of a product candidate or product;
- third parties with marketing and distribution rights to pitolisant or any future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with third parties, including disagreements over proprietary rights, contract interpretation or the preferred course
 of development, might cause delays or terminations of the research, development or commercialization of pitolisant or any future
 product candidates, might lead to additional responsibilities for us with respect to pitolisant or any future product candidates, or
 might result in litigation or arbitration, any of which would be time-consuming and expensive;
- third parties may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- third parties may infringe the intellectual property rights of other third parties, which may expose us to litigation and potential liability:
- if one of our third parties is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- relationships may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our relationships do not result in the successful discovery, development and commercialization of products or if a third party terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under any third party agreements we enter into, our development of pitolisant or any future product candidates could be delayed and we may need additional resources. Additionally, if any third party terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into relationships or do not have

sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected.

We expect to rely on third parties to conduct our clinical trials for pitolisant and any future product candidate that we decide to develop. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates on a timely basis or at all.

We will continue to rely upon third parties, including independent investigators, to conduct preclinical studies or clinical trials under agreements with universities, medical institutions, contract research organizations, or CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and study or trial sites, which may result in delays to our development timelines and increased costs.

We will have to rely heavily on third parties over the course of our preclinical studies and clinical trials and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol and regulatory requirements. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with Good Clinical Practice, or GCP, requirements for clinical trials, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of study or trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these clinical trials or perform additional clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP or other applicable requirements. In addition, our clinical trials must be conducted with drug products produced under current Good Manufacturing Practices, or cGMP, requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these regulations, which would delay the regulatory approval or commercialization process. Moreover, our business may be implicated if any of these third parties violates federal or state laws or regulations including fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any parties conducting our future clinical trials, if any, generally will not be our employees and, except for remedies that may be available to us under our agreements with the third parties conducting such clinical trials, if any, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our current and future product candidates. As a result, our financial results and the commercial prospects for our

current and future product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into contractual and other arrangements with alternative CROs or other third parties in a timely manner to meet projected clinical development deadlines or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially affect our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we experience delays in meeting or fail to meet the regulatory requirements for commercialization of our current or future potential product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We rely completely on third parties to manufacture and distribute our supply of WAKIX, including certain sole-source suppliers and manufacturers, and intend to rely on third parties to manufacture and distribute any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute commercial quantities of WAKIX. Our ability to commercially supply WAKIX depends, in part, on the ability of third-party manufacturers to supply and manufacture the raw materials, active pharmaceutical ingredient, or API, and other important components related to the manufacture of WAKIX. We also rely on third parties to package the finished product. These third-party manufacturers have limited experience manufacturing the raw materials and API for WAKIX to be supplied to patients in the United States. Prior to the approval of WAKIX, we experienced minor issues related to product specifications and other minor delays in supply related to our third-party suppliers and manufacturers. While we continue to work with our third-party suppliers and manufacturers to optimize the manufacturing process for WAKIX and will work to optimize the manufacturing process for any future product candidates, we cannot guarantee that even minor changes in the process will result in products that are safe and, where applicable, effective. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to successfully commercialize WAKIX.

We rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. For example, we rely on Interor S.A., Corden Pharma Chenôve SAS and Patheon UK Limited to provide intermediate supply ingredients, API and finished products, respectively. Additionally, we rely on our suppliers and manufacturers to purchase materials from other third parties. Any of our existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;
- · supply us with product that fails to meet regulatory requirements;

- become unavailable through business interruption or financial insolvency;
- · lose regulatory status as an approved source;
- be unable or unwilling to (i) honor current supply agreements or (ii) renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer technical processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA. Any need to find and qualify new suppliers or manufacturers could significantly delay production of WAKIX, adversely impact our ability to market WAKIX and adversely affect our business. There can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials beyond our currently forecasted needs. Any interruption in the supply of a drug substance or other material or in the manufacture of WAKIX could have a material adverse effect on our business, financial condition, operating results and prospects.

Additionally, although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMP for production of both drug substances and finished products. Facilities used by our contract suppliers and manufacturers to produce the drug substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. A number of our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of WAKIX is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize our product and we may be held liable for injuries sustained as a result. In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our product into the United States or other countries as a result of, among other things, regulatory agency approval requirements, taxes, tariffs, local import requirements such as import duties or inspections, incomplete or inaccurate import documentation or defective packaging. Any of these factors could adversely impact our ability to effectively commercialize WAKIX.

Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in science in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.

Competition from other biotechnology and pharmaceutical companies is intense and is expected to increase. There may be a number of companies pursuing the development of pharmaceuticals in rare neurological disorders, our area of focus. These companies may be very large, and may have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors may enable them to develop, obtain regulatory approval for or market competing products more quickly or effectively, making it extremely difficult for us to capture a share of the market for our product. We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. Generic competition often results in decreases in the prices at which branded products can be sold.

The commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. We also face competition from off-label uses of approved drugs. Additionally, the biotechnology and pharmaceutical industries are subject to rapid changes in science, and our competitors may develop and market products with improved therapeutic profiles relative to pitolisant or any future product candidates that would render pitolisant or any future product candidates noncompetitive.

We may need to increase the size and capabilities of our organization based on business need, and we may experience difficulties in managing our growth.

We commenced operations in 2017 and, as of March 31, 2020, had approximately 150 employees. As we advance the development of pitolisant in other indications and commercialize WAKIX as a treatment for EDS in adult patients with narcolepsy, we must continue to grow the size of the organization. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- effectively managing our development efforts, including the clinical development and FDA or other regulatory authority review processes for pitolisant or any future product candidates;
- effectively managing any third-party service providers involved in the development and manufacture of pitolisant or any future product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and commercialize WAKIX or any future product candidates will depend, in part, on our ability to effectively manage any future growth. Our management will have to dedicate a significant amount of its attention to managing these growth activities. In addition, we expect to incur additional costs in hiring, training and retaining such additional personnel.

If we are not able to effectively expand our organization, we may not be able to successfully execute the tasks necessary to further develop and commercialize pitolisant or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our management and scientific teams. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity award grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by changes in the price of our common stock that are beyond our control, and may at any time be insufficient to retain employees who receive more lucrative offers from other companies. Any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified operations, finance and accounting, quality and compliance, scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. If we are unable to attract, retain and motivate qualified and experienced personnel, it could harm our business, results of operations and financial condition. Even if we are successful in attracting and retaining such personnel, competition for such employees may significantly increase our compensation costs and adversely affect our business, results of operations and financial condition.

The loss of the services of any of our executive officers, key employees or consultants could seriously harm our ability to successfully implement our business strategy. Replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may hire part-time employees or use consultants. As a result, certain of our employees, officers, directors or consultants may not devote all of their time to our business, and may from time to time serve as employees, officers, directors and consultants of other companies.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, the manufacturing facilities of our third-party contract manufacturers or our or their distribution networks, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, or interruptions in the commercialization of WAKIX or our business operations. Natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities, the manufacturing facilities of our third-party contract manufacturers or our or their distribution networks, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs

may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

We depend on our information technology systems, and any failure of these systems could harm our business. Any real or perceived security breaches, loss of data, and other disruptions or incidents could compromise the privacy, security, integrity or confidentiality of sensitive information related to our business or prevent us from accessing critical information and expose us to liability and reputational harm, which could adversely affect our business, results of operations and financial condition.

We collect and maintain data and information that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including systems infrastructure operated and maintained by our third party suppliers or providers. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems and facilities to prevent an information compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization (including employees or contractors), lost or stolen devices, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through social engineering attacks, cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a real or perceived security breach affects our systems (or those of our third party providers or suppliers) or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of or other processing of personally identifiable information or clinical trial data, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH,

and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss, negative publicity, harm to our reputation, governmental investigation and/or enforcement actions, claims or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we begin to operate in foreign jurisdictions.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse laws, data privacy and security laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use or misrepresentation of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval process of the FDA is costly, lengthy and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for pitolisant in other potential indications for which we may seek to develop pitolisant, our business will be substantially harmed.

Although the commercialization of WAKIX is our primary focus, as part of our longer-term growth strategy, we plan to evaluate pitolisant in other indications and develop other product candidates. The

research, testing, manufacturing, labeling, approval, selling, import, export, pricing and reimbursement marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory agencies in the United States. Although we have obtained regulatory approval for WAKIX in the United States for the treatment of EDS in adults with narcolepsy, it is possible that we may not obtain regulatory approval for pitolisant for other indications, including for the treatment of cataplexy, for which we may seek such approval, or for any other product candidates we may seek to develop in the future. We received a Complete Response Letter, or CRL, for pitolisant for the treatment of cataplexy in adult patients with narcolepsy. Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process.

The FDA can delay, limit or deny approval of a drug candidate for many reasons or require us to conduct additional preclinical or clinical testing, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective, or the clinical and other benefits may be deemed to not outweigh the candidate's risks;
- the FDA might not approve our trial design and analysis plan;
- the FDA may not find the data from nonclinical and clinical studies and trials sufficient or may disagree with our interpretation of data from nonclinical or clinical studies:
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing the active ingredient in our product candidates;
- clinical inspection(s) by the FDA or other regulatory authorities may result in unacceptable findings that could negatively impact approval of pitolisant;
- · the FDA might not accept or deem acceptable a third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

Prior to obtaining approval to commercialize a drug candidate in the United States, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such drug candidates are safe and effective for their intended uses. The number of nonclinical and clinical studies and trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. If pitolisant fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval for other indications, our business and results of operations will be materially and adversely harmed. Additionally, if the FDA requires that we conduct additional clinical trials, places limitations on pitolisant in our label, delays approval to market pitolisant or limits the use of pitolisant, our business and results of operations may be harmed.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or

comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we fail to obtain and sustain an adequate level of coverage and reimbursement for WAKIX and other product candidates by third-party payors, sales would be adversely affected.

Successful sales of WAKIX and any other product candidates that may receive regulatory approval depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. Commercial third-party payors, such as private health insurers and health maintenance organizations, also decide which medications they will pay for and establish reimbursement levels, though commercial third-party payors often follow CMS' reimbursement determinations. The availability of coverage and the extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of WAKIX or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- · safe, effective and medically necessary;
- · appropriate for the specific patient;
- · cost-effective; and
- · neither experimental nor investigational.

We cannot be sure that reimbursement will be available for WAKIX and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor can be an expensive and time-consuming process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. The industry competition to be included in third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement, often leads to downward pricing pressures on pharmaceutical products. In addition, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average manufacture price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, there may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses.

Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

While we have obtained coverage for WAKIX from certain third-party payors, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use WAKIX unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of WAKIX. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We may suffer loss of corporate reputation due to industry-wide legislative or public scrutiny of our pricing decisions and practices within an increasingly price-sensitive environment.

Despite obtaining formulary approval from certain third-party payors, sometimes with prior authorization or other formulary restrictions and requirements, including documented failure or inadequate response to alternative treatments, we expect to experience pricing pressures in connection with the sale of WAKIX due to the trend toward cost containment, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are questioning the coverage of, and challenging the prices charged for medical products and services, and many third-

party payors limit coverage of, or reimbursement for, newly approved health care products. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for WAKIX.

These cost-control initiatives could decrease the price we have established for WAKIX, which could result in product revenues being lower than anticipated. The pricing, coverage and reimbursement of WAKIX must be adequate to support a commercial infrastructure. If the price for WAKIX decreases or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, our revenue, gross margins and prospects for profitability will suffer.

While we have not taken any steps to attain regulatory or patent approvals in any specific markets outside of the United States, we plan to explore obtaining additional licensing rights from Bioprojet to expand into international markets with WAKIX. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries will likely put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for WAKIX. Accordingly, in markets outside the United States, the reimbursement for WAKIX may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

WAKIX has been approved by the FDA for the treatment of EDS in adult patients with narcolepsy. Regulatory approval is limited by the FDA to the specific indication for which approval has been granted and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing pitolisant for other indications. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of pitolisant for unapproved or "off-label" uses, resulting in damage to our reputation and business.

While we received approval for the indication of the treatment of EDS in adult patients with narcolepsy, WAKIX is not indicated for the treatment of cataplexy in adult patients with narcolepsy. We therefore are prohibited from promoting WAKIX for the treatment of cataplexy in narcolepsy unless we are granted FDA approval for such indication. The FDA strictly regulates the promotional claims that may be made about prescription products, and WAKIX may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or pharmaceutical companies on off-label use. If the FDA determines that our promotional activities constitute promotion of an off-label use, it could

request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

WAKIX or any of our future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, reduce the commercial attractiveness of a prescribing label or result in significant negative consequences following regulatory approval, if approved.

Clinical trials of WAKIX or other product candidates we may develop could reveal a high and unacceptable incidence and severity of undesirable side effects. Undesirable side effects could adversely affect patient enrollment in clinical studies, cause us or regulatory authorities to interrupt, delay or halt clinical studies or result in the delay, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities. Undesirable or adverse side effects also could result in regulatory authorities mandating a more restrictive prescribing label for the product, which, in turn, could limit the market acceptance of the product even if approved for marketing and commercialization.

Drug-related side effects could result in potential product liability claims. We believe our product liability insurance coverage is sufficient in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or maintain coverage at all to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations, business and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, significant negative media attention, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our current product candidate or any future product candidate, product recalls, restrictions on labeling, marketing or promotion, decreased demand for our product candidates, if approved for marketing, and loss of revenue.

Additionally, if we or others later identify undesirable side effects caused by WAKIX, either in the field or in clinical trials in other potential indications for which we develop pitolisant, or in clinical trials for other product candidates, a number of potentially significant negative consequences could result, including but not limited to:

- the delay, prevention or withdrawal of approvals by regulatory authorities;
- the requirement of additional warnings on the prescribing label;
- the requirement of a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining
 the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to
 assure safe use:
- designation as a controlled substance by the U.S. Drug Enforcement Administration, or DEA;
- litigation and the potential to be held liable for harm caused to patients; and
- an adverse effect on our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of pitolisant and could significantly harm our business, results of operations, financial condition and prospects.

We have never commercialized a product candidate prior to WAKIX and we may lack the necessary expertise, personnel and resources to successfully commercialize WAKIX or any other potential product candidates that receive regulatory approval on our own or together with collaborators.

WAKIX is our first commercialized product. Prior to this, our operations had been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no in-house manufacturing, distribution or supply capabilities. To achieve commercial success of WAKIX or any other product candidate, if approved, we will have to develop our own manufacturing, distribution and supply capabilities or outsource these activities to a third party.

We are early in our commercialization efforts. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

While we have received five years of NCE exclusivity for WAKIX, manufacturers may seek to launch generic products following the expiration of the applicable exclusivity period we obtain, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could materially and adversely affect our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects or patients required for clinical trials of pitolisant in additional indications or any other product candidate
 may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the
 number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given
 clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or
 facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or
 quality of pitolisant or any other product candidate or other materials necessary to conduct clinical trials of our product
 candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
 and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs of the institutions in which clinical trials are being conducted or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the

imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive results from our ongoing clinical trials of pitolisant for the treatment of narcolepsy, or any other clinical trial or preclinical studies in animals that we conduct, could mandate repeated or additional clinical trials and could result in changes to or delays in clinical trials in other indications. We do not know whether any clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market pitolisant for our initial or potential additional indications, or any other product candidate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for pitolisant for initial or potential additional indications, or any other product candidate, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of pitolisant for potential additional indications or any other product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market pitolisant or any other product candidate would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of pitolisant or any other product candidate.

In addition, prior to our acquisition of the rights to pitolisant, we had no involvement with or control over the nonclinical or clinical development of pitolisant. Additionally, pursuant to our collaboration agreement with Bioprojet, we will rely on data generated by Bioprojet in connection with seeking regulatory approval of pitolisant in the territories in which we have rights to develop and commercialize pitolisant. We are dependent on Bioprojet having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to pitolisant, having correctly collected and interpreted the data from these trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to predecessors could result in increased costs and delays in the development of pitolisant for additional indications, which could adversely affect our ability to generate any future revenue from sales of pitolisant, if approved for additional indications.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, "topline" or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available topline data, and the results and related findings and conclusions are subject to change following completion of the study or a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, "topline" or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. "Topline" data also

remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, "topline" data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, "topline" or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Furthermore, any negative results or new safety signals we or third parties may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in our clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. In addition, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop pitolisant or any future product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Even though the FDA granted orphan drug designation to pitolisant for the treatment of narcolepsy, we may not be able to obtain or maintain orphan drug marketing exclusivity for this product candidate or any other product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Pitolisant was granted orphan drug designation for the treatment of narcolepsy in 2010. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. Under the FDA's regulations, the FDA will deny orphan drug exclusivity to a designated drug upon approval if the FDA has already approved another drug with the same active ingredient for the same indication, unless the drug is demonstrated to be clinically superior to the previously approved drug. The applicable exclusivity period is seven years in the United States. Orphan drug exclusivity in the United States may be unavailable where the indication for which the product candidate is approved is broader than the orphan-designated indication, or is otherwise different from the orphan-designated indication. For example, the FDA granted orphan drug designation for pitolisant for the treatment of narcolepsy. This means that pitolisant for the treatment of cataplexy in adult patients with narcolepsy may not be covered by the scope of any orphan drug exclusivity that we may obtain in the future. Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the candidate from competition. WAKIX may face additional competition because different drugs with a different active moiety can still be approved for the same condition. Even after an approved drug is granted orphan exclusivity, exclusivity may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition following approval. In addition, the FDA can subsequently approve products with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We are subject to ongoing regulatory obligations and continued regulatory review with respect to WAKIX, which will result in significant additional expense. Additionally, WAKIX could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with WAKIX.

WAKIX is subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, distribution, import, export, record keeping and

submission of safety and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Our regulatory approval for WAKIX for the treatment of EDS in adult patients with narcolepsy, and any other regulatory approvals we may receive for pitolisant or any future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, which must comply with applicable GCP regulations. We could also be asked to conduct post marketing clinical studies to verify the safety and efficacy of future product candidates in general or in specific patient subsets. For example, as a part of the regulatory approval for WAKIX for the treatment of EDS in adult patients with narcolepsy, we are required to conduct post-marketing studies in women exposed to pitolisant in pregnancy, including a registry-based observational cohort study to assess maternal, fetal, and infant outcomes of women exposed to pitolisant during pregnancy, and another study of a different design such as a case control study or a retrospective cohort study using electronic medical record data, and a lactation study.

We will also be required to report certain adverse events and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for WAKIX. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote WAKIX for indications or uses for which it does not have FDA approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process.

If a regulatory agency discovers previously unknown problems with WAKIX, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on the product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- · issue warning or untitled letters;
- impose civil or criminal penalties, including product seizures and injunctions;
- · limit or suspend regulatory approval;
- · suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities, on the manufacturing of our products, or on the labeling or marketing of our products; or
- · seize or detain products or require a product recall or withdrawal of the products from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with

ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from WAKIX or future product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from the sale of WAKIX or future product candidates, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

The regulatory requirements and policies may change, and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, may face government enforcement action and our business will suffer.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, certain policies of the Trump administration may affect our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. The laws that affect our current and future operations include, but are not limited to:

 the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for, or to induce or reward, or in return for, either the referral of an individual

for, or the purchase, lease, order or recommendation of, any good, facility, item, or service for which payment may be made, in whole or in part, under any U.S. federal healthcare programs, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws, such as the False Claims Act, or FCA, which imposes significant penalties
 and can be enforced by private citizens through civil qui tam actions, and prohibits individuals or entities from, among other
 things, knowingly presenting, or causing to be presented, to the U.S. federal government, false, fictitious or fraudulent claims for
 payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a
 false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money
 to the U.S. federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection
 with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to
 the government for government price reporting purposes, and allegedly providing free product to customers with the expectation
 that the customers would bill federal health care programs for the product. In addition, the government may assert that a claim
 including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for
 purposes of the FCA;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration
 to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's
 selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program,
 unless an exception applies;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to
 execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a
 material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits,
 items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of
 the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended HITECH, and its implementing regulations, which imposes privacy, security and breach reporting
 obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually
 identifiable health information upon covered entities subject to the rule, such as health plans, healthcare clearinghouses and
 healthcare providers and their respective business associates and independent contractors that perform certain services for
 them that involve the use or disclosure of individually identifiable health information on their behalf. HITECH also created new
 tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates,
 and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the
 federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that
 potentially harm consumers;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- state law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to
 items or services reimbursed by any third-party payor, including commercial insurers, and may be broader in scope than their
 federal equivalents;
- federal transparency requirements detailing interactions with and payments to healthcare providers, such as the federal reporting
 requirements under the Physician Payments Sunshine Act, which requires, among other things, certain manufacturers of drugs,
 devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program, with
 specific exceptions, to report annually to the HHS information related to payments and other transfers of value provided to
 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care
 professionals starting January 1, 2022, and teaching hospitals and physician ownership and investment interests, including such
 ownership and investment interests held by a physician's immediate family members. Failure to submit required information may
 result in civil monetary penalties;
- state laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers and other potential referral sources, state laws that require drug manufacturers to file reports relating to pricing information and marketing expenditures, state and local laws requiring the registration of pharmaceutical sales representatives; and other state laws and regulations that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar healthcare and data protection laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR.

Ensuring that our business operations and current and future arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including, without limitation, our patient support and financial assistance programs, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil, administrative and criminal penalties, damages, fines, the curtailment or restructuring of our operations, contractual damages, disgorgement, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve

allegations of non-compliance with these laws, the exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to market pitolisant, if approved, and adversely impact our financial results. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the applicable regulatory agencies or the courts, and their provisions are open to a variety of interpretations.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Clinical practice guidelines and recommendations published by various organizations could have significant influence on the use of WAKIX

Professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to the healthcare and patient communities. The recommendations of these groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of WAKIX or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of WAKIX.

Product candidates we develop in the future may be classified as controlled substances, the making, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Product candidates we develop in the future may be classified as controlled substances, which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the federal Controlled Substances Act of 1970, or CSA, and regulations of the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our products or product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates, and, in the case of our approved products, the ability to produce and distribute our products in the volume needed to meet commercial demand.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates

containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our approved products or product candidates that are classified as controlled substances.

Enacted and future healthcare legislative changes may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States, the European Union and other some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to the pharmaceutical industry and our potential product candidates are the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program for branded and generic drugs;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to
 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's
 Medicaid rebate liability;
- · expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and

• a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing challenges in the Fifth Circuit Court and the U.S. Supreme Court, the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation and regulations designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review 2020 relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in April of 2018, CMS published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, Congress has indicated that it will continue to seek new legislative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. It would require HHS to directly negotiate drug prices with manufacturers. It is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business.

Additionally, in 2019, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. HHS has also begun implementation of the Trump administration Blueprint, soliciting feedback on some of these measures and, immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2029. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into

law in March 2020, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one additional year, through 2030. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review 2020 relationship between pricing and manufacturer patient programs. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates, once approved, or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with everincreasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing

requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect to participate in and have certain price reporting obligations to the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data we would have to report on a monthly and quarterly basis to the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicaid Drug Rebate Program. These data include, among other things, the average manufacturer price, or AMP, and, in the case of innovator products, the best price, or BP, for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA or other legislation or regulation could affect our 340B ceiling price calculations and negatively impact our results of operations commercializing pitolisant. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have our products that we successfully commercialize paid for with federal funds under the Medicaid program and purchased by certain federal agencies and grantees,

we also would have to participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we would be obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard).

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and antimony laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, which could prevent new products and services from being developed or commercialized in a timely manner, which could negatively affect our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the U.S. Securities and Exchange Commission, or SEC, have had to furlough critical FDA, SEC and other governmental employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which harm our business. Similarly, a prolonged government shutdown could prevent the timely review of any of our patent applications by the U.S. Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled.

Further, upon completion of this offering and in our operations as a public company, future government shutdowns could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA reviews proposed product names, considering both the potential for the name to lead to medical errors due to confusion with other product names and whether the proposed name is overly fanciful, misleadingly implies unique effectiveness or composition, or contributes to overstatement of product efficacy, minimization of risk, broadening of product indications or unsubstantiated superiority. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, on a combination of patents, trademarks and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future product candidates. Our success depends in large part on our licensor's ability to obtain and maintain patent protection in the United States with respect to WAKIX and our ability to obtain and maintain patent protection in the United States and any other relevant foreign jurisdictions with respect to any future product candidates that we develop. We seek to ensure that our current and future licensors obtain appropriate patent protection to all product candidates that we license from them. The patent prosecution process is expensive and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Our patent portfolio comprises four U.S. patents exclusively licensed to us from Bioprojet. One U.S. patent, No. 8,207,197 has claims directed to a polymorph, i.e. a specific crystalline form, of pitolisant and, methods for preparing that polymorph of pitolisant, which is expected to expire in February 2029 without taking into consideration any possible patent term extension. A second U.S. patent, No. 8,486,497, has claims directed to methods of treating excessive daytime sleepiness by administering pitolisant, which is expected to expire in September 2029 without taking into consideration any possible patent term extension. With all applicable patent term adjustments available and granted to us, the term of the last-to-expire pitolisant-related patent in our portfolio extends to September 2029.

The patents that we in-license now or the patents and patent applications that we own or in-license in the future may not have patentable claims that protect our current and future product candidates in the relevant jurisdictions where we intend to commercialize such products. There is no assurance that we and our licensor are aware of all potentially relevant prior art relating to future patent applications. As such, the patent examiner may find prior art that can prevent a patent from issuing

from a pending patent application. During the patent examination process, we or our licensor may be required to narrow the pending claims to overcome prior art, a process that may limit the scope of patent protection. Even if patents do successfully issue based on our future patent applications, and even if the issued patents cover our current and future product candidates, including their compositions formulation, method of manufacture, and method of use, third parties may challenge our issued patents' validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us in the future could deprive us of rights necessary for the successful commercialization of any of our current or future product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we may own or in-license in the future with respect to our current and future product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates, it could dissuade other companies from collaborating with us to develop future product candidates, and threaten our ability to commercialize our current and future product candidates. Notably, pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could have an adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and challenged at the USPTO and may also affect patent litigation. The USPTO has developed and continues to develop new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it remains unclear what impact the Leahy-Smith Act, subsequent rulemaking, and judicial interpretation of the Leahy-Smith Act and regulations will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition. Moreover, future changes to the patent laws of the United States and foreign jurisdictions may adversely affect the term, scope, validity and enforceability of our or our licensor's

patent rights. For example, a new bill (Terminating the Extension of Rights Misappropriated Act, or TERM Act, H.R. 3199) percolating through the United States Congress aims to reduce the term of certain drug patents in order to ease generic entry and increase competition.

The inventorship and ownership rights for patents that we in-license or may own or in-license in the future may be challenged by third parties. Such challenges could result in loss of exclusive rights to such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or require us to obtain a license from such third parties on commercially reasonable terms to secure exclusive rights. If any such challenges to inventorship or ownership were asserted, there is no assurance that a court would find in our favor or that, if we choose to seek a license, such license would be available to us on acceptable terms or at all.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in pre- and post-issuance opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications, whether owned or in-licensed now or in the future, is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our licensed patents may be challenged in the courts or patent offices in the United States. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after the filling of the earliest non-provisional application to which the patent claims priority. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We may be required to disclaim a portion of patent term in order to overcome double patenting rejections from the patent office, thus potentially shortening our exclusivity period. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future product candidates.

We have licensed certain intellectual property rights covering pitolisant from Bioprojet, and we may license intellectual property rights from others in the future. If, for any reason, our license agreement with Bioprojet or any future licensor is terminated or we otherwise lose the rights associated with a license, it could adversely affect our business. Our license agreement with Bioprojet imposes, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be

required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term for our current and future product candidates, our business may be harmed.

Our commercial success will largely depend on our licensor's ability to obtain and maintain patent and other intellectual property in the United States for pitolisant, and our target indications, and our ability to maintain obtain and maintain patent and other intellectual property in the United States for any product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States.

Depending upon the timing, duration and specifics of FDA marketing approval of our current and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request.

If we or our licensor are unable to extend the expiration date of our or their existing patents or obtain new patents with longer expiry dates, as applicable, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our current and future product candidates can be challenged by third parties.

One or more third parties may challenge the current patents, or future patents within our portfolio, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug containing pitolisant, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a

paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or future patents within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing, for example, pitolisant, and relies in whole or in part on studies conducted by or for us.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our current and future product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain patents and patent applications, whether owned or in-licensed now or in the future, covering any of our current or future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business

We may need to acquire or license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our current and future product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our current and future product candidates, if approved, would likely be delayed.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our current or future product candidates.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may in the future be developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.

Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our current and future product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our current and future product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation

expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our current and future product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current and future product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current and future product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current product candidate in any jurisdiction.

It is possible that we and our current and future licensors will fail to identify patentable aspects of research and development output before it is too late to obtain patent protection. The patent applications that we may own or in-license in the future may fail to result in issued patents with claims that cover our current and future product candidates. We and our current and future licensors may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of the patent applications, which may result in such patents being narrowed, invalidated or held unenforceable.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively affect our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively affect our ability to develop and market our products.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate the patents of our licensor or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims,

which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that an asserted patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the asserted patent does not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of asserted patents at risk of being invalidated or interpreted narrowly and could put a related patent application at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we may license in the future, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our in-licensed patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued numerous precedential opinions in recent years narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, non-transferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Any trademarks we have obtained or may obtain may be infringed or be successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our current and future product candidates that are approved for marketing from the products of our competitors. For example, we are marketing pitolisant for the treatment of adult patients with EDS in adult patients with narcolepsy under the brand name WAKIX, which we have licensed from Bioprojet. We may design or create new trademarks and apply to register them, our trademark applications may not be approved in the United States or any relevant foreign jurisdiction. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Being a Public Company

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over

financial reporting for the fiscal year beginning January 1, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal controls procedures on a quarterly basis.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and finance staff and consultants with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal controls over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal controls over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline. If we were to subsequently elect instead to comply with these public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that have not made this election.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three fiscal years; or (iv) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC.

Our management team has limited experience managing a public company.

Our chief executive officer does not have experience managing a public company, interacting with public company investors or complying with the increasingly complex laws pertaining to public companies. Our management team, as a whole, may not successfully or efficiently manage the transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management, particularly from our chief executive officer, and could divert their attention away from the day-to-day management of our business, which could adversely affect our revenue, business, results of operations and financial condition.

Risks Related to This Offering and Ownership of Our Common Stock

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution.

The offering price of our common stock is substantially higher than the net tangible book value per share of our common stock, which on a pro forma basis was \$ per share of our common stock as of March 31, 2020. Based on the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. This means that you will pay a higher price per share than the amount of our total tangible assets, less our total liabilities, divided by the number of shares of common stock outstanding. Furthermore, if the underwriters exercise their over-allotment option or our previously issued options, warrant and other rights to acquire common stock at prices below the assumed initial public offering price are exercised, you will experience further dilution. In addition, you may also experience additional dilution if options or other rights to purchase our common stock that are outstanding or that we may issue in the future are exercised or converted or we issue additional shares of our common stock at prices lower than our net tangible book value at such time. See "Dilution."

No public market for our common stock currently exists, and an active trading market may not develop or be sustained following this offering.

Prior to this offering, there has been no public market for our common stock. Although we have applied to have our common stock listed on the Nasdaq , an active trading market may not

develop following the closing of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. The initial public offering price was determined by negotiations between us and the underwriters and may not be indicative of the future prices of our common stock.

Our share price may be volatile, and you may be unable to sell your shares at or above the offering price.

The market price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to pitolisant or any other potential product candidates or our competitors' products and product candidates;
- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcements of innovations by us or our competitors;
- overall conditions in our industry and the markets in which we operate;
- market conditions or trends in the biotechnology industry or in the economy as a whole;
- addition or loss of significant healthcare providers or other developments with respect to significant healthcare providers;
- · changes in laws or regulations applicable to pitolisant or any other potential product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- · additions or departures of key personnel;
- · competition from existing products or new products that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, and our ability to obtain intellectual property protection for our products;
- · security breaches;
- · litigation matters;
- · announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

- · the expiration of contractual lock-up agreements with our executive officers, directors and stockholders; and
- · general economic and market conditions.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our directors, officers and principal stockholders beneficially own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2020, our directors, officers, five percent or greater stockholders, and their respective affiliates beneficially owned in the aggregate approximately % of our outstanding voting stock and, upon the completion of this offering, that same group will beneficially own in the aggregate approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares). As a result, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, and approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Based on shares of common stock outstanding as of March 31, 2020, the conversion of all of our preferred stock immediately prior to the closing of this offering into shares of common stock and the payment of an accrued dividend to holders of our convertible preferred stock upon the closing of this offering in the aggregate amount of shares of our common stock, upon the closing of this offering, we will have shares of common stock outstanding.

All of the common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers for at least 180 days after the date of this prospectus, subject to certain extensions. See also the section of this prospectus captioned "Shares Eligible For Future Sale."

The underwriters may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements with the underwriters prior to expiration of the lock-up period. For more information regarding the lock-up agreements with the underwriters, see the section of this prospectus captioned "Underwriting."

The holders of shares of common stock, or %, based on shares outstanding on an as-converted basis as of March 31, 2020, the conversion of all of our preferred stock immediately prior to the closing of this offering into shares of common stock and the payment of an accrued dividend to holders of our convertible preferred stock upon the closing of this offering in the aggregate amount of shares of our common stock, will be entitled to rights with respect to registration of such shares under the Securities Act pursuant to a registration rights agreement between such holders and us. See "Description of Capital Stock—Registration Rights" below. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. We intend to file a registration statement on Form S-8 under the Securities Act to register the shares subject to outstanding stock options under the Equity Incentive Plan as of the date of this prospectus and shares of common stock for issuance under our 2020 Plan. The 2020 Plan will provide for automatic increases in the shares reserved for grant or issuance under the plan which could result in additional dilution to our stockholders. Once we register the shares under these plans, they can be freely sold in the public market upon issuance and vesting, subject to a 180-day lock-up period and other restrictions provided under the terms of the applicable plan and/or the award agreements entered into with participants.

Our management has broad discretion in the use of the net proceeds from this offering and may not use the net proceeds effectively.

Our management will have broad discretion in the application of the net proceeds of this offering. We cannot specify with certainty the uses to which we will apply these net proceeds. The failure by our management to apply these funds effectively could adversely affect our ability to continue maintaining and expanding our business.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if our operating results do not meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- · addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- · regulatory developments affecting pitolisant;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;

- · the achievement and timing of milestone payments under our existing collaboration and license agreements; and
- the level of underlying demand for WAKIX and customers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

We may issue additional securities following the closing of this offering. In the future, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, consultants and directors pursuant to our equity incentive plans. If we sell common stock, convertible securities or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. Furthermore, we are party to a Credit Agreement with OrbiMed that contains negative covenants that limit our ability to pay dividends. For more information, see the section of this prospectus captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws will contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a
 takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our
 amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of
 at least 66.67% of the shares entitled to vote at an election of directors;
- · prohibiting stockholder action by written consent;
- · limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we are subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law, or the DGCL. Under Section 203 of the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions. For more information, see the section of this prospectus captioned "Description of Capital Stock—Anti-Takeover Provisions."

Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- · any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our current or former directors, officers, employees or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our
 amended and restated bylaws (as either may be amended from time to time) or as to which the DGCL confers jurisdiction on the
 Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

By becoming a stockholder in our Company, you will be deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to

find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our
 request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if
 such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of
 the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was
 unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification:
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements within the meaning of the federal securities laws. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the operating results and financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, statements about:

- · our commercialization efforts and strategy for WAKIX;
- the rate and degree of market acceptance and clinical utility of WAKIX, pitolisant in additional indications, if approved, and any
 other product candidates we may develop or acquire, if approved;
- our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications;
- · our ongoing and planned clinical trials;
- our ability to expand the scope of our license agreement with Bioprojet;
- the availability of favorable insurance coverage and reimbursement for WAKIX;
- · the impact of the COVID-19 pandemic;
- the timing of and our ability to obtain regulatory approvals for pitolisant for other indications as well as any other product candidates:
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;
- · our commercialization, marketing and manufacturing capabilities and strategy;
- · significant competition in our industry;
- our intellectual property position;
- loss or retirement of key members of management;
- failure to successfully execute our growth strategy, including any delays in our planned future growth;
- · our failure to maintain effective internal controls; and
- · the impact of government laws and regulations.

In this prospectus, the words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "predict," "potential" and similar expressions, as they relate to our company, our business and our management, are intended to identify forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Forward-looking statements speak only as of the date of this prospectus. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Unless otherwise indicated, information contained in this prospectus concerning our industry, including industry statistics and forecasts, competitive position and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and other third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, projections, forecasts, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed and forecasts in the estimates made by the independent parties and by us.

Unless expressly stated, we obtained industry, business, market and other data from the reports, publications and other materials and sources listed below. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources unless otherwise expressly stated or the context otherwise requires.

- U.S. Food and Drug Administration, The Voice of the Patient Narcolepsy ("Voice of the Patient"), June 2014
- Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018 (conducted by Versta Research on our behalf, and in collaboration with Narcolepsy Network, and respondents included 200 U.S. adults with narcolepsy, 1,203 U.S. adults without narcolepsy, and 251 physicians currently in clinical practice who have treated patients with narcolepsy in the last two years)

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission, or SEC, as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate, based upon an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus), that we will receive net proceeds from this offering of approximately \$ million (or \$ million if the underwriters exercise their option to purchase additional shares of common stock in full), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$ million to fund the potential new indications for pitolisant in PWS, MD and pediatric narcolepsy through clinical development; and
- the remainder for working capital, business development opportunities, a potential milestone payment to Bioprojet and general
 corporate purposes, including to support the continued commercialization of WAKIX in the United States.

We expect that the proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund the potential new indications for pitolisant in PWS, MD and pediatric narcolepsy through clinical development. However, if we are granted approval for a cataplexy indication in adult patients with narcolepsy and are required to pay the resulting \$102.0 million milestone payment to Bioprojet, we believe that existing cash and cash equivalents, together with the net proceeds of this offering, will not be sufficient to fund the potential new indications for pitolisant in PWS, MD and pediatric narcolepsy through clinical development, regulatory approval and commercialization. As such, we will need to finance the development of such additional indications from cash from operations or subsequent equity or debt financings or a combination thereof.

Our expected use of proceeds from this offering represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We may also use a portion of the proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets. Although we have no specific agreements, commitments or understandings with respect to any in-licensing activity or acquisition, we evaluate these opportunities and engage in related discussions with other companies from time to time.

The amount and timing of our actual expenditures will depend on numerous factors, including the results of our research and development efforts, the timing and outcome of any ongoing or future preclinical studies or clinical trials, and the timing and outcome of regulatory submissions. As a result, our management will have broad discretion over the use of the proceeds from this offering.

Pending the use of the proceeds from this offering, we may invest the proceeds in interest- bearing, investment-grade securities, certificates of deposit or government securities.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each 1,000,000 share increase (decrease) in the number of shares offered in this offering would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming that the price per share for the offering remains at \$ (which is the midpoint of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

CAPITALIZATION

The following table sets forth the cash and capitalization as of March 31, 2020, as follows:

- · on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock; (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock; and (iii) the effectiveness of our amended and restated certificate of incorporation, in each case immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give effect to the pro forma adjustments described in the preceding clause and to reflect the
 issuance and sale by us of shares of common stock in this offering at an assumed initial public offering price of \$ per
 share (which is the midpoint of the range set forth on the cover page of this prospectus), after deducting the estimated
 underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

	As of March 31, 2020		
			Pro Forma
		Pro	As
	Actual	forma	adjusted
	(in thou	ısands, except	t share
		data)	
Cash and cash equivalents	\$ 71,517		
Long-term debt, net	192,177		
Convertible preferred stock warranty liability	3,505		
Convertible preferred stock, par value \$0.00001 per share; 323,030,000 shares authorized,			
318,510,205 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro			
forma and pro forma as adjusted	422,643		
Preferred stock, par value \$0.00001 per share; no shares authorized, issued and outstanding, actual;			
shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	_		
Common stock, par value \$0.00001 per share; 424,000,000 shares authorized, 64,125,058 shares			
issued and outstanding, actual; shares authorized, shares issued and outstanding, pro			
forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1		
Additional paid-in capital	_		
Accumulated deficit	(472,331)		
Total stockholders' (deficit) equity	(472,330)		
Total capitalization	145,995		
·			

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase or decrease each of cash and cash equivalents, total stockholders' (deficit) equity and total capitalization on a pro forma as adjusted basis by approximately \$ million, assuming the number of shares

offered, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each 1,000,000 share increase or decrease in the number of shares offered in this offering would increase or decrease each of cash and cash equivalents, total stockholders' (deficit) equity and total capitalization on a pro forma as adjusted basis by approximately \$ million, assuming that the price per share for the offering remains at \$ (which is the midpoint of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The information in the table above excludes:

- shares of common stock issuable upon exercise of outstanding stock options granted under our Equity Incentive Plan as of March 31, 2020, at a weighted average exercise price of \$ per share;
- shares of common stock available for future issuance under our Equity Incentive Plan as of March 31, 2020; and
- shares of our common stock that will become available for future issuance under our 2020 Plan, which will become
 effective in connection with the completion of this offering.

DIVIDEND POLICY

We currently intend to retain all available funds and any future earnings to fund the development, commercialization and growth of our business, and therefore we do not anticipate declaring or paying any cash dividends on any class of our common stock in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. Any such determination will also depend upon our business prospects, results of operations, financial condition, cash requirements and availability and other factors that our board of directors may deem relevant. Our Credit Agreement with OrbiMed prohibits us from declaring and paying cash dividends.

The terms of our current certificate of incorporation provide that, upon the conversion of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock into shares of our common stock upon the closing of this offering, each holder of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock will receive a cumulative accrued dividend calculated at a rate per annum of 10% of the applicable issue price of such series of preferred stock, in each case, compounded annually, payable, at the determination of our board of directors, in either (i) shares of common stock or (ii) cash in an aggregate amount equal to the cumulative accrued dividend. We intend to pay the cumulative accrued dividend in shares of common stock. Assuming we pay the cumulative accrued dividend in shares of common stock, the cumulative accrued dividend will be issued to each holder of preferred stock as of immediately prior to the closing of this offering a number of shares of common stock equal to (x) the aggregate amount of the accrued dividend held by such holder and not previously paid as of immediately prior to the closing of this offering divided by (y) the actual price per share of common stock sold to the public in this offering. Based on the midpoint of the price range set forth on the cover page of this prospectus, we expect to issue (i) shares of our common stock for cumulative accrued dividends to holders of our Series A shares of our common stock for cumulative accrued dividends to holders of our Series B preferred stock and preferred stock, (ii) shares of our common stock to holders of our Series C preferred stock. Stock dividends will not be paid on any shares of our (iii) common stock purchased in this offering.

Accordingly, you may need to sell your shares of our common stock to realize a return on your investment, and you may not be able to sell your shares at or above the price you paid for them. See "Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases."

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of March 31, 2020 was \$(472.3) million, or \$(7.37) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 64,125,058 shares of our common stock outstanding as of March 31, 2020.

Our pro forma net tangible book value (deficit) as of March 31, 2020 was \$ million, or \$ per share. Pro forma net tangible book value per share is determined by subtracting our total liabilities from the total book value of our tangible assets and dividing the difference by the number of shares of common stock deemed to be outstanding, after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering in shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock which becomes due and payable to such holders upon the conversion of their convertible preferred stock upon the closing of this offering.

After giving further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2020, would have been \$ million, or \$ per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$ per share to new investors purchasing shares of common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock. The following table illustrates this dilution:

Assumed initial public offering price per share of common stock		\$
Historical net tangible book value (deficit) per share as of March 31, 2020	\$(7.37)	
Increase per share attributable to the conversion of outstanding preferred stock and payment of accrued dividend		
Pro forma net tangible book value per share as of March 31, 2020 before this offering		
Increase in pro forma as adjusted net tangible book value per share attributable to investors in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new common stock investors in this offering		

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (which is the midpoint of the price range listed on the cover page of this prospectus) would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately \$, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after the offering would be \$ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$ per share and the dilution in pro forma as adjusted net tangible book value to new investors would be \$ per share, in each case assuming an initial public offering price of \$ per share, which is the midpoint of the price range listed on the cover page of this prospectus.

The following table summarizes, as of March 31, 2020, after giving effect to this offering, the number of shares of our common stock purchased from us, the total consideration paid, or to be paid, to us and the average price per share paid, or to be paid, by existing stockholders and by the new investors. The calculation below is based on an assumed initial public offering price of \$ per share (which is the midpoint of the price range listed on the cover page of this prospectus) before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Shares Purchased		Total Consider	ration	Average price	
umber F	Percent	Amount	Percent	per share	
	%	\$	 %	\$	
	100%	\$	100%	\$	
-		<u>Percent</u> %	Imber Percent Amount % \$	Imber Percent Amount Percent % \$ %	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the total consideration paid by new investors and the total consideration paid by all stockholders by \$ million, assuming the number of shares offered by us remains the same and after deducting estimated underwriting discounts and commissions but before estimated offering expenses.

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of our common stock and excludes:

- shares of common stock issuable upon exercise of outstanding stock options granted under our Equity Incentive Plan as of March 31, 2020, at a weighted average exercise price of \$ per share;
- shares of common stock available for future issuance under our Equity Incentive Plan as of March 31, 2020; and
- shares of our common stock that will become available for future issuance under our 2020 Plan, which will become
 effective in connection with the completion of this offering.

To the extent any of these outstanding options are exercised, there will be further dilution to new investors. To the extent all of such outstanding options had been exercised as of ______, the pro forma as adjusted net tangible book value per share after this offering would be \$ _____, and total dilution per share to new investors would be \$ _____.

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of our common stock held by the existing stockholders will decrease to approximately % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to common stock outstanding after this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present our summary consolidated financial data. We have derived the selected consolidated statements of operations data for the three months ended March 31, 2020 and 2019 and the selected consolidated balance sheet data as of March 31, 2020 from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations data for the year ended December 31, 2019 and 2018 and the summary consolidated balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited interim condensed consolidated financial statements on a basis substantially consistent with our audited consolidated financial statements as of and for the year ended December 31, 2019, and the unaudited interim condensed consolidated financial statements include all normal recurring adjustments necessary for a fair statement of the financial information set forth in those unaudited interim condensed consolidated financial statements. You should read the following selected consolidated financial data in conjunction with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, related notes and other financial information included elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and is qualified in its entirety by the consolidated financial statements, related notes and other financial information included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of our future results, and our operating results for the three-month period ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 or any other interim periods or any future year or period.

Consolidated Statement of Operations Data: (U.S. dollars in thousands except share and per share data)		ree Months ed March 31, 2020		ee Months ed March 31, 2019	-	ear Ended cember 31, 2019		ear Ended cember 31, 2018
Net product revenue	\$	19,840	\$		\$	5,995	\$	
Cost of product sales		3,474		_		1,577		_
Gross profit		16,366		_		4,418		_
Operating expenses:								
Research and development	\$	3,431	\$	52,990	\$	69,595	\$	12,372
Sales and marketing		13,254		6,191		44,318		16,861
General and administrative		9,290		3,962		36,409		12,206
Total operating expenses		25,975		63,143		150,322		41,439
Operating loss		(9,609)		(63,143)		(145,904)		(41,439)
Loss on debt extinguishment		(22,639)		_				_
Interest income (expense)		(6,372)		122		(6,073)		1,541
Loss before taxes		(38,620)		(63,021)		(151,977)		(39,898)
Income taxes		<u> </u>		_		<u> </u>		<u> </u>
Net loss and comprehensive loss	\$	(38,620)	\$	(63,021)	\$	(151,977)	\$	(39,898)
Accumulation of yield on preferred stock		(10,445)		(8,314)		(35,231)		(30,185)
Net loss available to common stockholders	\$	(49,065)	\$	(71,335)	\$	(187,208)	\$	(70,083)
Loss per share:								
Loss per share, basic and diluted(1)(2)	\$	(0.77)	\$	(1.12)	\$	(2.93)	\$	(0.96)
Weighted average number of common stock, basic and diluted	6	64,000,341	6	3,888,976	6	3,891,677	72	2,765,366
Pro Forma net loss per share, basic and diluted (unaudited)(1)(2)	\$		\$		\$			
Pro Forma weighted average shares of common stock outstanding, basic and diluted (unaudited)								_

⁽¹⁾ See Note 13 to our financial statements for the three months ended March 31, 2020 appearing at the end of this prospectus for

further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

See Note 15 to our financial statements for the year ended December 31, 2019 appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders. (2)

Consolidated Balance Sheet Data: (U.S. dollars in thousands except share and per share data)	March 31, 2020	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 71,517	\$ 24,457	\$ 83,523
Working capital ⁽¹⁾	74,048	11,605	79,453
Total assets	\$ 163,094	\$ 106,703	\$ 89,282
Warrant liability	3,505		
Long-term debt, net	192,177	97,946	_
Convertible preferred stock	422,643	411,277	324,201
Total stockholders' (deficit) equity	(472,330)	(422,862)	(242,673)

⁽¹⁾ We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients with rare neurological disorders living with unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action, or MOA, specifically designed to increase histamine signaling in the brain by binding to H3 receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of our lead indication, excessive daytime sleepiness, or EDS, in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance. We plan to pursue label expansion for WAKIX in narcolepsy in pediatric patients and engage with the FDA in pursuit of pediatric exclusivity. We currently expect to initiate a Phase 3 clinical trial in pediatric patients in the second half of 2021 in pursuit of indications for both EDS and cataplexy. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication for WAKIX. We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through H₃ receptors and histamine signaling. We are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome, or PWS, and myotonic dystrophy, or MD. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020, with topline results expected in the first half of 2022. We are also planning to commence a Phase 2 clinical trial in adult patients with MD in the first half of 2021, with topline results expected in the second half of 2022, subject to receiving authorization to proceed under an Investigational New Drug application, or IND. Beyond these indications, we intend to further explore pitolisant in other rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.

Pitolisant was developed by Bioprojet Société Civile de Recherche, or Bioprojet, and approved by the European Medicines Agency, or EMA, in 2016 for the treatment of narcolepsy in adult patients with or without cataplexy. We acquired an exclusive license to develop, manufacture and commercialize pitolisant in the United States pursuant to our license agreement with Bioprojet, or the Bioprojet License Agreement, in July 2017. See "—Strategic Agreement—License and Commercialization Agreement with Bioprojet" for further information regarding the Bioprojet License Agreement. Pitolisant was granted Orphan Drug Designation for the treatment of narcolepsy by the FDA in 2010. It received Breakthrough Therapy designation for the treatment of cataplexy in patients with narcolepsy and Fast Track status for the treatment of EDS and cataplexy in patients with narcolepsy in April 2018.

Our operating subsidiary, Harmony Biosciences, LLC, was formed in May 2017. We were formed in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and we converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017. In February 2020, we changed our name to Harmony Biosciences Holdings, Inc. Our operations to date have consisted of

building and staffing our organization, acquiring the rights to pitolisant, raising capital, opening an Investigational New Drug, or IND, for pitolisant, initiating an Expanded Access Program, or EAP, for pitolisant for appropriate patients in the United States, preparing and submitting our NDA for pitolisant, gaining NDA approval for WAKIX for EDS in adult patients with narcolepsy, and launching and commercializing WAKIX in the United States. In addition, we have initiated or intend to initiate clinical development programs in PWS, MD and pediatric narcolepsy to pursue potential new indications. We have funded our operations through private placements of our convertible preferred stock as well as borrowings under a term loan agreement. We raised an aggregate of \$295.0 million through offerings of our Series A and B convertible preferred stock in September 2017 and January 2018, respectively. In February 2019, we entered into a multi-draw term loan agreement with CRG Servicing LLC, or CRG, for an aggregate of \$200.0 million, or the Loan Agreement of which \$102.5 million was outstanding as of December 31, 2019. In August 2019, we raised an additional \$50.0 million in gross proceeds from the sale of our Series C convertible preferred stock. On January 9, 2020, we entered into a credit agreement with OrbiMed Royalty & Credit Opportunities III, LP, or OrbiMed, for an aggregate of \$200.0 million, or the Credit Agreement. We paid off all of our obligations under the Loan Agreement with proceeds from the Credit Agreement. As of March 31, 2020, there was \$200.0 million outstanding under the Credit Agreement.

In the three months ended March 31, 2020, we generated \$19.8 million of net product revenues and for the year ended December 31, 2019, we generated \$6.0 million in net product revenues. We expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution as well as significant expenses related to further clinical development programs with pitolisant for potential new indications. We have incurred significant operating losses since inception and expect to continue to incur operating losses. For the three months ended March 31, 2020 and 2019, we incurred net losses of \$38.6 million and \$63.0 million, respectively. We had an accumulated deficit as of March 31, 2020 of \$472.3 million. For the years ended December 31, 2019 and 2018, we recorded net losses of \$152.0 million and \$39.9 million, respectively.

As of March 31, 2020, our cash, cash equivalents and restricted cash were \$72.3 million. We believe that the expected revenue generated from sales of WAKIX, our existing cash and cash equivalents, together with the anticipated net proceeds from this offering, will enable us to fund our commercialization efforts, operating expenses, clinical trials, product development and capital requirements through at least December 31, 2021. See "—Liquidity and Capital Resources". However, we have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect. If this offering is not successful, there is no guarantee that we will have sufficient capital to fund operations. See "—Going Concern" below.

We expect our expenses to increase substantially as we continue to:

- · commercialize WAKIX in the United States for the treatment of EDS in adult patients with narcolepsy;
- incur sales and marketing costs to support the commercialization of WAKIX and any additional product candidates;
- pay royalties and make milestone payments to Bioprojet for the license of WAKIX;
- incur manufacturing costs for WAKIX and any additional product candidates;
- implement post-approval requirements related to WAKIX;
- · actively pursue an indication for WAKIX for the treatment of cataplexy in adult patients with narcolepsy;
- · conduct clinical trials in PWS and MD;

- conduct a pediatric narcolepsy program in pursuit of an indication and extension of patent exclusivity;
- conduct earlier stage research and development activities for pitolisant;
- · hire additional personnel;
- invest in measures to protect and expand our intellectual property;
- · incur interest expenses in conjunction with our debt facility;
- seek regulatory approvals for pitolisant or any additional product candidates that successfully complete clinical development;
- conduct additional clinical trials in pursuit of potential new indications for pitolisant; acquire certain ex-U.S. rights for WAKIX from Bioprojet and subsequently seek foreign regulatory approvals for WAKIX in certain of those jurisdictions; acquire or in-license other assets and technologies; and
- incur additional costs associated with being a public company.

In addition, as we continue to commercialize pitolisant, we will be obligated to make certain milestone payments to the licensor. For example, previously, we made a milestone payment of \$75.0 million plus an additional \$2.0 million extension fee to Bioprojet in November 2019 and August 2019, respectively, for the approval of EDS in adult patients with narcolepsy. See "Business—Strategic Agreement—License and Commercialization Agreement with Bioprojet" elsewhere in this prospectus for further information regarding the Bioprojet License Agreement. Our net losses may fluctuate significantly quarterly or yearly, depending on the timing of milestone payments, clinical trials, research and development expenditures and commercialization expenses.

We may need to raise additional funding to support our continuing operations and pursue our growth strategy, inclusive of our commercial strategy. We have started to generate revenue from WAKIX and until such time as we can generate sufficient revenues, we may need to finance our operations through the sale of equity securities, debt financings or other capital resources, including potential collaborations with third parties or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly scale back or discontinue the development of pitolisant and commercialization of WAKIX, and/or one or more possible indications or delay our efforts to expand our product pipeline. We expect to have positive cash flows from operations within the next two years; however, there is no guarantee of us achieving such results.

COVID-19 Business Update

With the global impact of the COVID-19 pandemic, we have developed a response strategy including establishing cross-functional response teams and implementing business continuity plans to manage the impact of the COVID-19 pandemic on our employees, patients and our business. We experienced limited financial impacts during the first quarter of 2020. However, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, we expect that our business, financial condition, results of operations and growth prospects will be adversely affected in future quarters.

In accordance with guidance issued by the Centers for Disease Control and Prevention, the World Health Organization and local authorities, in March 2020, our workforce, including field-based teams, transitioned to working remotely. Our organization mobilized to enable our employees to accomplish our most critical goals in new ways, leveraging positivity, innovation and prioritization of

resources to overcome new obstacles. To supplement the launch of WAKIX in the midst of the COVID-19 pandemic, we began leveraging remote technologies to engage with our targeted healthcare professionals, or HCPs. On April 6, 2020, we launched a virtual sales education platform for our field sales team to use in sales outreach. Through May 31, 2020, we executed over 500 educational programs as we continue to convert new prescribers to WAKIX. On April 20, 2020, we launched virtual key opinion leader speaker programs designed to engage with our targeted HCPs. Through this initiative, we have reached over 300 HCP targets through May 31, 2020. In addition to rolling out new technologies and collaboration tools, we have implemented processes and resources to support our employees in the event an employee receives a positive COVID-19 diagnosis. We are now developing plans related to reopening our sites and enabling our employees to return to work in our offices, and the field, which plans will take into account applicable public health authority and local government guidelines and which are designed to ensure employee safety.

Commercialization

With respect to our commercialization activities, we believe that the evolving effects of the COVID-19 pandemic are having an impact on demand and new patient starts, primarily due to our inability to conduct in-person interactions with HCPs, cancellations of patient appointments and a reprioritization of healthcare resources toward COVID-19. Due to the nature of the pandemic, we are not able to accurately predict the duration or extent of these impacts on our sales efforts. Beginning in March 2020, we transitioned our field-based sales, market access, and medical employees to remote work and suspended work-related travel and in-person customer interactions with healthcare professionals and customers. Since then, we have been utilizing technology to continue to engage HCPs virtually to support patient care for people living with narcolepsy. As clinics and institutions begin to allow in-person interactions pursuant to health authority and local government guidelines, our field teams will start to re-initiate in-person interactions with healthcare professionals and customers, but the timing and level of engagement will vary by account and region and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19 may occur.

For WAKIX, any impact on demand could be related to a reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, the reduced ability to see patients due to cancelled appointments and reprioritization of healthcare resources toward COVID-19. Going forward, an impact may potentially be seen on patient compliance and persistence with WAKIX treatment, and the ability to pay for their prescriptions.

Depending on the scale and ultimate duration of the COVID-19 pandemic and the extent of an economic slowdown, widespread unemployment and resulting loss of employer-sponsored insurance coverage, we may experience a shift from commercial payor coverage to government payor coverage or an increase in demand for patient assistance and/or free drug programs, which would adversely affect access to our products and our net sales.

Supply Chain

We currently expect to have adequate global supply of WAKIX through 2020. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the COVID-19 pandemic.

Our manufacturing partners in France and the United States continue to be operational. If the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as transatlantic freight, FedEx, UPS and postal delivery, we could experience disruptions to our supply chain and operations with associated delays in the manufacturing and supply of our products.

Research and Development

We are seeing a COVID-19-related impact on our clinical trial activities. We have taken measures and put contingency plans in place to implement remote and virtual approaches, including using telemedicine for remote clinic visits to perform efficacy assessments and sending out licensed HCPs to each patient to collect safety assessments (e.g. labs, electrocardiograms) as required by the protocols. We are also performing remote data monitoring where possible and all of these measures are being instituted to maintain patient safety and trial continuity while preserving study integrity. We are seeing an impact on our ability to initiate trial sites and enroll patients in our clinical programs and have delayed planned clinical trials associated with PWS and MD. In addition, we rely on contract research organizations, or CROs, or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time, or reemerges in the future, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Corporate Development and Other Financial Impacts

The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of domestic and global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. The pandemic could also impact our ability to do in-person due diligence, negotiations, and other interactions to identify new opportunities.

While we expect the COVID-19 pandemic to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of and revenues from our approved products, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of or reemergence of outbreaks, governmental "stay-athome" orders and travel restrictions, quarantines, social distancing and business closure requirements in the United States, France, and other countries, and the effectiveness of actions taken globally to contain and treat the disease.

Corporate Response

We are supporting our local communities and patient-focused organizations in COVID-19 relief efforts including through corporate donations to charitable organizations to our communities in which we operate where the needs related to the impact of COVID-19 are greatest.

Financial Operations Overview

Revenue

We did not generate any revenue from inception until the fourth quarter of 2019. Our current product, WAKIX, was approved by the FDA for the treatment of EDS in adult patients with narcolepsy in August 2019 and became commercially available in November 2019. For the three months ended March 31, 2020, we had \$19.8 million of net product revenue and for the year ended December 31, 2019, we had \$6.0 million in net product revenue.

Total revenue consists of net sales of WAKIX, which was commercially launched in November 2019. Net sales represent the gross sales of WAKIX less provisions for product sales

discounts and allowances. At this time, these provisions include trade allowances, rebates to government and commercial entities, and discounts. Although we expect net sales to increase over time, the provisions for product sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in our accrual estimates. For further discussion of the components of Revenue see "—Critical Accounting Policies and Significant Judgments and Estimates."

Cost of Product Sales

Cost of product sales includes manufacturing and distribution costs, the cost of the drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs and salaries of employees involved with production. We began capitalizing inventory upon FDA approval of WAKIX. A portion of the inventory sold during the three months ended March 31, 2020 was produced prior to FDA approval and, therefore, expensed previously as research and development expense in 2019 in the amount of \$1.3 million. Excluded from cost of product sold is amortization of acquired developed technology of \$1.8 million and \$0 in the three months ended March 31, 2020 and March 31, 2019, respectively.

Previously expensed inventory that was manufactured in anticipation for commercialization preapproval has not had a material impact on our historical results of operations and is not expected to have a material impact on future results of operations. Further, previously expensed inventory has not had a material impact on our gross margin percentage historically, and we do not anticipate a material impact on our gross margin percentage once our previously expensed inventories have been exhausted. We do expect that our cost of product sales will increase moderately in the near term as we ramp up production and sales infrastructure to meet expected demand for WAKIX.

The shelf life of our product is three years from date of manufacture, with earliest expiration of current inventory expected to be September 2021. Due to the high rate of inventory turnover generated by our commercial launch efforts for WAKIX, as of the date of this prospectus we do not expect any of our existing inventory to reach obsolescence. We will continue to reassess whether we expect additional inventory to reach obsolescence in future periods as demand for WAKIX and the rate of inventory turnover evolves.

Research and Development Expenses

Our research and development expenses have primarily been limited to the license of the rights to pitolisant, the establishment of an EAP to provide appropriate patients with pitolisant at no cost as part of a clinical trial to assess safety prior to the approval of WAKIX, the preparation of the NDA, and the initiation of a development program for new indications for pitolisant in patients with PWS, MD and pediatric narcolepsy. Research and development activities account for a significant portion of our operating expenses and these costs are expensed as incurred. Following the closing of this offering, we expect to significantly increase our research and development efforts as we continue to pursue an indication for the treatment of cataplexy in adult patients with narcolepsy, conduct clinical trials in patients with PWS, MD and pediatric narcolepsy, and continue to expand our product-candidate pipeline. Research and development expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our research and development personnel;
- direct third-party costs such as expenses incurred under agreements with CROs, and contract manufacturing organizations, or CMOs;
- manufacturing costs in connection with producing materials for use in conducting preclinical studies and clinical trials;

- other third-party expenses directly attributable to the development of our product candidates; and
- amortization expense for assets used in research and development activities.

We currently have one product, WAKIX, and do not currently track our internal research and development expenses on an indication-by-indication basis as they primarily relate to personnel, early research and consumable costs, which are deployed across multiple programs. A significant portion of our research and development costs are external costs, such as fees paid to consultants, central laboratories, contractors, CMOs and CROs in connection with our clinical development activities.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, milestone payments, and the cost of submitting an NDA to the FDA (and/or other regulatory authorities). We expect our research and development expenses to be significant over the next several years as we advance our current clinical development programs and prepare to seek regulatory approval for additional product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any additional indications for pitolisant or other product candidates that we move forward for regulatory approval. We have begun to generate net revenue from sales of WAKIX; however we are unable to predict when if ever we would generate sufficient cash inflows from WAKIX or other product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates, including uncertainty related to:

- the duration, costs and timing of clinical trials of our current and future indication expansion programs and new product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- the impact of the COVID-19 pandemic on the ability to initiate new clinical trials and/or maintain the continuity of ongoing clinical trials that could be impacted by future shelter-in-place orders and needs of the health care system to focus on managing patients affected by COVID-19;
- · receiving Bioprojet's consent to pursue additional indications for pitolisant;
- the acceptance of INDs for our planned clinical trials or future clinical trials;
- · the successful and timely enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- · the successful completion of preclinical studies and clinical trials;
- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- the entry into collaborations to further the development of our product candidates;
- · obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; and

· successfully launching our product candidates and achieving commercial sales, if and when approved.

A change in the outcome of any of these variables with respect to the development of any of our programs or any product candidate we develop would significantly change the costs, timing and viability associated with the development and/or regulatory approval of such programs or product candidates.

Sales and Marketing Expenses

Our sales and marketing expenses have primarily been limited to the market development and launch activities of WAKIX for EDS in adult patients with narcolepsy. Market development and commercial launch activities account for a significant portion of the overall company operating expenses and are expensed as they are incurred. We expect our sales and marketing expenses to increase in the near- and mid-term to support our EDS in adult patient with narcolepsy indication and expand our portfolio with the anticipated growth from potential additional indications. Sales and marketing expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our sales and marketing personnel;
- healthcare professional-related expenses, including marketing programs, healthcare professional promotional medical education, disease education, conference exhibits and market research;
- patient-related expenses, including patient awareness and education programs, disease awareness education, patient reimbursement programs, patient support services and market research;
- · market access expenses, including payer education, and services to support the continued commercialization of WAKIX; and
- · secondary data purchases (i.e. patient claims and prescription data), data warehouse development and data management.

In addition, these expenses include external costs such as website development, media placement fees, agency fees for patient, medical education and promotional expenses, market research and analysis secondary data expenses, conference fees, consulting fees and travel expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our personnel in executive, legal, finance and accounting, human resources, and other administrative departments. General and administrative expenses also consist of office leases, interest expenses, and professional fees, including legal, tax and accounting and consulting fees.

We anticipate that our general and administrative expenses will increase in the future to support our continued commercialization efforts, ongoing and future potential research and development activities, and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees paid to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with

maintaining compliance with the requirements of Nasdaq and the Securities and Exchange Commission, or the SEC, insurance and investor relations costs. If any of our current or future indication expansion programs or new product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Paragon Agreements

We are party to a management services agreement, or the Management Services Agreement, with Paragon Biosciences, LLC, or Paragon, entered into on September 22, 2017, pursuant to which Paragon provides us with certain professional services. In exchange for services provided to us under the Management Services Agreement, we pay Paragon a management fee of \$0.3 million per each calendar month. This fee is reduced to \$0.2 million per each calendar month starting in October 2020. We intend to terminate the Management Services Agreement upon the consummation of this offering. Upon termination, we will owe Paragon a termination fee of \$ million. See "Certain Relationships and Related Party Transactions—Related Party Agreements in Effect Prior to this Offering—Management and Other Agreements" for further information.

We are also party to a right of use agreement with Paragon whereby we have access to and the right to use certain office space leased by Paragon in Chicago, Illinois. Through March 31, 2020, we paid fees of \$0.5 million pursuant to this agreement.

Loss on Debt Extinguishment

Loss on debt extinguishment consists primarily of costs of extinguishment of debt during the period related to the prepayment of the Loan Agreement with CRG.

Interest Income (Expense), Net

Interest Income / Interest Expense

Interest income (expense), net consists primarily of interest expense on debt facilities and amortization of debt issuance costs, and is offset by interest income earned on our cash balances.

Consolidated Statements of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

The following table sets forth our results of operations for the three months ended March 31, 2020 and 2019.

	Three Months Ended	Three Months Ended	Char	ange	
	March 31, 	March 31, 2019	Amount	%	
		(dollars in t			
Net product revenue	\$ 19,840	\$ —	\$ 19,840	n/a	
Cost of product sales	3,474	_	3,474	n/a	
Gross profit	16,366	_	16,366	n/a	
Operating expenses:					
Research and development	\$ 3,431	\$ 52,990	\$(49,559)	(93.5)%	
Sales and marketing	13,254	6,191	7,063	114.1%	
General and administrative	9,290	3,962	5,328	134.5%	
Total operating expenses	25,975	63,143	(37,168)	(58.9)%	
Loss on debt extinguishment	(22,639)	_	(22,639)	n/a	
Interest income (expense), net	(6,372)	122	(6,494)	(5,323.0)%	
Loss before provision for income taxes	(38,620)	(63,021)	24,401	(38.7)%	
Provision for income taxes				n/a	
Net loss	\$(38,620)	\$(63,021)	\$ 24,401	(38.7)%	

Net Product Revenue

Net product revenue increased to \$19.8 million for the three months ended March 31, 2020 compared to no sales in the same period in 2019 due to the commercial launch of WAKIX on November 1, 2019.

Cost of Product Sales

Cost of product sales increased to \$3.5 million for the three months ended March 31, 2020 compared to no costs in the same period in 2019 due to the commercial launch of WAKIX on November 1, 2019.

Research and Development Expenses

Research and development expenses decreased to \$3.4 million for the three months ended March 31, 2020 compared to \$53.0 million for the same period in 2019. The decrease was primarily due to a milestone payment in February 2019 of \$50.0 million associated with the Bioprojet License Agreement upon the acceptance of our NDA for WAKIX by the FDA.

Sales and Marketing Expenses

Sales and marketing expenses were \$13.3 million for the three months ended March 31, 2020 compared to \$6.2 million for the same period in 2019. The increase was primarily related to field sales force personnel expenses and related field sales operations associated with the commercial launch of WAKIX.

General and Administrative Expenses

General and administrative expenses were \$9.3 million for the three months ended March 31, 2020, compared to \$4.0 million for the same period in 2019 due primarily to intangible asset amortization, fair value of warrants and public filing costs.

Loss on Debt Extinguishment

Loss on debt extinguishment was \$22.6 million for the three months ended March 31, 2020, compared to zero for the same period in 2019, consisting primarily of costs of extinguishment of debt during the period related to the prepayment of the Loan Agreement with CRG.

Interest Income (Expense), Net

Interest expense, net was \$6.4 million for the three months ended March 31, 2020, compared to interest income, net, of \$0.1 million for the same period ended 2019. Interest expense, net, for the three months ended March 31, 2020 consisted primarily of interest on the outstanding debt facility, amortization of debt issuance costs, partially offset by interest income earned on our cash balances.

Income Taxes

For interim periods, we estimate the annual effective income tax rate and apply the estimated rate to the year-to-date income or loss before income taxes. The effective income tax rates for the three months ended March 31, 2020 and 2019 was 0.0% and 0.0%, respectively. Currently, we have recorded a full valuation allowance against its net deferred tax assets, primarily related to federal and state net operating losses. These losses were approximately \$147.8 million and \$139.3 million, respectively, as of December 31, 2019.

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018.

	-	Year Ended December 31, 2019		ear Ended cember 31,	Chang	nge	
	De			2018	Amount	%	
			(dollars in thou	ısands)		
Net product revenue	\$	5,995	\$	_	\$ 5,995	n/a	
Cost of product sales		1,577		_	1,577	n/a	
Gross profit		4,418		_	4,418	n/a	
Operating expenses:							
Research and development	\$	69,595	\$	12,372	\$ 57,223	462.5%	
Sales and marketing		44,318		16,861	27,457	162.8%	
General and administrative		36,409		12,206	24,203	198.3%	
Total operating expenses		150,322		41,439	108,883	262.8%	
Interest income (expense), net		(6,073)		1,541	(7,614)	(494.1)%	
Loss before provision for income taxes		(151,977)		(39,898)	(112,079)	280.9%	
Provision for income taxes		· _′		·	· -	n/a	
Net loss	\$	(151,977)	\$	(39,898)	\$(112,079)	280.9%	

Net Product Revenue

Net product revenue increased to \$6.0 million for the year ended December 31, 2019 compared to no sales for the same period in 2018 due to the commercial launch of WAKIX on November 1, 2019.

Cost of Product Sales

Cost of product sales increased to \$1.6 million for the year ended December 31, 2019 compared to no costs for the same period in 2018 due to the commercial launch of WAKIX on November 1, 2019.

Research and Development Expenses

Research and development expenses increased to \$69.6 million for the year ended December 31, 2019 compared to \$12.4 million for the same period in 2018. This increase was primarily due to a milestone payment associated with the Bioprojet License Agreement upon the acceptance of our NDA for WAKIX by the FDA and clinical costs associated with our EAP.

Sales and Marketing Expenses

Sales and marketing expenses increased to \$44.3 million for the year ended December 31, 2019 compared to \$16.9 million for the same period in 2018, primarily due to field sales force personnel and related expenses, and sales force operations due to the commercial launch of the WAKIX and patient engagement and marketing activities.

General and Administrative Expenses

General and administrative expenses increased to \$36.4 million for the year ended December 31, 2019 compared to \$12.2 million for the same period in 2018, primarily due to non-employee stock awards, the legal settlement with our former CEO, additional fees associated with this offering and amortization of intangible asset.

Interest Income (Expense), Net

Interest expense, net, increased to \$6.1 million for the year ended December 31, 2019 compared to interest income, net, of \$1.5 million for the same period in 2018. Interest expense, net, for the year ended December 31, 2019 consisted primarily of the payment of interest on the Loan Agreement and amortization of debt issuance costs, and was offset by interest income earned on our cash balances.

Income Taxes

At December 31, 2019, we had federal net operating loss, or NOL, carryforwards of \$147.8 million, with pre-2018 federal NOLs expiring in 2037 whereas our NOLs arising in 2018, and subsequent years, have an unlimited carryforward period. At December 31, 2019, we had state NOL carryforwards of \$139.3 million that begin to expire in 2037. In light of these considerations as well as uncertainty as to when we might generate taxable income, we have recorded a full valuation allowance of \$100.7 million as of December 31, 2019. The amount of the net deferred tax asset considered realizable could be adjusted in the future based on changes in positive and negative evidences subject to evaluation, including estimates of taxable income.

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily with proceeds from sales of our convertible preferred stock and borrowings under (i) our Loan Agreement with CRG and (ii) our Credit Agreement with OrbiMed. From our inception through March 31, 2020, we have received aggregate proceeds of \$345.0 million from sales of our convertible preferred stock. As of March 31, 2020, we had cash, cash equivalents and restricted cash of \$72.3 million and accumulated deficit of \$472.3 million. As of March 31, 2020, we had outstanding debt, net of issuance costs, of \$192.2 million.

On February 28, 2019, we entered into the Loan Agreement with CRG for an aggregate of \$200.0 million of which \$102.5 million was outstanding at December 31, 2019. On January 9, 2020, we entered into the Credit Agreement with OrbiMed for an aggregate of \$200.0 million and paid off all of our obligations under the Loan Agreement. The Credit Agreement matures on January 9, 2026 and bears an interest rate of the greater of (a) LIBOR or (b) 2.00% per annum, plus 11.00% per annum. When the LIBOR rate is no longer used post-2021, the Prime Rate will be used in the determination of the interest rate. The Credit Agreement requires compliance with certain financial covenants, including minimum net revenue thresholds and cash balance requirements (which include maintaining minimum liquidity of \$12.5 million), and financial reporting requirements. We have been in compliance with the financial covenants under the Credit Agreement since it was entered into on January 9, 2020. The Credit Agreement also contains certain negative restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event we, engage in new lines of business, incur additional indebtedness or liens, make certain investments, make certain payments, pay cash dividends, merge with other companies or consummate certain changes of control, acquire other companies, transfer or dispose of certain assets, liquidate or dissolve, amend certain material agreements, enter into sale and leaseback transactions, enter into various other specified transactions, and change our name, location, executive office or executive management without notice.

We currently estimate that we will use the net proceeds from this offering to fund the clinical development of additional indications for pitolisant in PWS, MD and pediatric narcolepsy, and for working capital, business development opportunities, a potential milestone payment to Bioprojet and general corporate purposes, including to support the continued commercialization of WAKIX in the United States. We may need additional funding to complete the clinical development of, seek regulatory approval for and commercially launch future potential indications for pitolisant.

We have started to generate revenue from WAKIX but, until such time as we generate sufficient revenue, we may finance our cash needs through a combination of equity securities, debt financings or other capital resources, and potential collaboration, license or development agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2020 and 2019 and the years ended December 31, 2019 and 2018:

(U.S. dellara in the upanda)	Three months Ended March 31,	Three months Ended March 31,	Year Ended December 31,	Year Ended December 31,
(U.S. dollars in thousands)	2020	2019	2019	2018
Net cash used in operating activities	\$(26,702)	\$(10,595)	\$ (75,436)	\$ (38,799)
Net cash used in investing activities		(50,032)	(127,149)	(1,342)
Net cash provided by financing activities	73,762	18,216	143,769	21,615
Net increase/(decrease) in cash, cash equivalents and restricted cash	47,060	\$(42,411)	\$ (58,816)	\$ (18,526)

Operating Activities

Net cash used in operating activities increased to \$26.7 million for the three months ended March 31, 2020 compared to \$10.6 million the same period in 2019. This increase was primarily attributable to company growth associated with the commercial launch of WAKIX.

Net cash used in operating activities for the three months ended March 31, 2020 consisted of our net loss of \$38.6 million adjusted for non-cash items of \$22.6 million associated with loss on extinguishment of debt and \$3.0 million related to intangible amortization and fair value of warrants. Net working capital excluding cash decreased by \$14.6 million due to company growth and the commercial launch of WAKIX.

Net cash used in operating activities for the three months ended March 31, 2019 consisted of net loss of \$63.0 million adjusted for a reclassification of \$50.0 million to investing activities related to a milestone payment associated with the Bioprojet License Agreement.

Net cash used in operating activities increased to \$75.4 million for the year ended December 31, 2019 compared to \$38.8 million for the same period in 2018. This increase was primarily attributable to company growth associated with the commercial launch of WAKIX.

Net cash used in operating activities for the year ended December 31, 2019 primarily consisted of our net loss of \$152.0 million adjusted for non-cash items, \$52.0 million reclassification to investing activities related to a milestone payment associated with the Bioprojet License Agreement, \$9.9 million related to stock compensation expense, \$2.8 million of intangible amortization. Net working capital excluding cash increased \$8.2 million.

Net cash used in operating activities for the year ended December 31, 2018 primarily consisted of a net loss of \$39.9 million.

Investing Activities

There was no net cash used in investing activities for the three months ended March 31, 2020, compared to \$50.0 million for the same period in 2019. This change was primarily due to \$50.0 million of milestone payments associated with the Bioprojet License Agreement.

Net cash used in investing activities increased to \$127.1 million for the year ended December 31, 2019 compared to \$1.3 million for the same period in 2018. This increase was primarily attributable to \$52.0 million of milestone payments associated with the Bioprojet License Agreement and \$75.0 million related to the acquisition of an intangible asset.

Net cash used in investing activities for the year ended December 31, 2018 consisted of the purchase of property and equipment for our new corporate headquarters.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2020 was \$73.8 million, which primarily consisted of \$194.2 million associated with the OrbiMed Credit Agreement net of issuance costs offset with \$120.6 million of repayment and exit fees associated with the CRG Loan Agreement.

Net cash provided by financing activities for the three months ended March 31, 2019 was \$18.2 million, which primarily consisted of borrowings under the CRG Loan Agreement net of issuance costs.

Net cash provided by financing activities for the year ended December 31, 2019 was \$143.8 million, which primarily consisted of \$94.8 million associated with the CRG Loan Agreement net of issuance costs and \$48.9 million in proceeds from the issuance of our Series C Preferred Stock net of issuance costs.

Net cash provided by financing activities for the year ended December 31, 2018 was \$21.6 million, which primarily consisted of \$24.8 million in proceeds from the issuance of our Series A Preferred Stock and Series B Preferred Stock, net of issuance costs, offset by a \$3.2 million repurchase of common stock.

Outlook

Based on the expected net proceeds from this offering, our research and development plans and our timing expectations related to the development of our clinical programs to pursue indications for PWS, MD and pediatric narcolepsy, we believe that the expected revenue generated from sales of WAKIX, our existing cash and cash equivalents, together with the anticipated net proceeds from this offering will enable us to fund our operating expenses, clinical development, sales and marketing, interest expense and capital expenditure requirements through at least December 31, 2021. However, we have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect. If this offering is not successful, there is no guarantee that we will have sufficient capital to fund operations. See "—Going Concern" below.

The amount and timing of future funding requirements will depend on many factors, including, but not limited to:

- · the success of our commercialization of WAKIX for EDS in adult patients with narcolepsy;
- · the effect of competing technological and market developments;
- · the cost and timing of manufacturing activities;
- the payment of licensing fees, royalties and potential milestone payments to Bioprojet;
- · the outcome, timing and cost of meeting regulatory requirements established by the FDA and other regulatory authorities;
- the potential expansion of our current development programs to seek new indications for pitolisant, potential new development programs for additional indications, and related general and administrative support;

- the initiation, progress, timing, and results of our clinical trials through all phases of development for pitolisant as a treatment for other indications and any other product candidates;
- the willingness of the FDA and other comparable regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for the review and approval of pitolisant for other potential indications or of any other product candidates;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties
 against us for pitolisant or future product candidates;
- the cost of acquiring rights to other pharmaceutical products in the future to further develop and commercialize;
- · the cost of general operating expenses;
- · the cost of interest expense in conjunction with our debt facility;
- the cost of sales, marketing and distribution capabilities for WAKIX and the cost of establishing our sales and marketing our
 product candidates where those product candidates are approved and where we choose to commercialize our products on our
 own;
- · the costs of operating as a public company; and
- the COVID-19 pandemic could adversely impact our business including sales of WAKIX, our preclinical studies and clinical trials.

Contractual Obligations and Commitments

As of March 31, 2020, our commitments consisted of operating leases for our corporate headquarters in Plymouth Meeting, Pennsylvania, for approximately 15,651 square feet, which expires in May 2024, and office space in Chicago, Illinois, for approximately 4,450 square feet, which expires in December 2020. The following table summarizes our contractual obligations as of March 31, 2020.

		Payments Due by Period				
		Less Than			More Than	
	Total	Total One Year 1–3 Years 3–5 Years			Five Years	
	·	(in thousands)				
Operating lease obligations	\$2,128,726	\$645,089	\$1,442,696	\$40,940	_	

Under the Bioprojet License Agreement, we have obligations that are contingent upon future events such as our achievement of regulatory and commercial milestones and are required to make royalty and trademark payments in connection with the sale of products. In February 2019, we achieved one of our regulatory milestones, FDA file acceptance, and as a result, a milestone payment of \$50.0 million was due to Bioprojet and was paid in February 2019. Further, upon achieving FDA approval for WAKIX for the treatment of EDS in adult patients with narcolepsy, we paid Bioprojet an FDA approval milestone payment of \$75.0 million in November 2019 and an additional payment of \$2.0 million in August 2019. As of March 31, 2020, we were unable to estimate the timing and likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. See the section titled "Business—License Agreement with Bioprojet" for additional information regarding our license agreement with Bioprojet.

We enter into contracts in the normal course of business with clinical trial sites, clinical and commercial supply manufacturers, and other services and products for operating purposes. These

contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above

Going Concern

The consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred operating losses and negative cash flows from operations since inception. As March 31, 2020, we have an accumulated deficit of \$472.3 million. Management expects to continue to incur operating losses and negative cash flows. In addition, we are subject to potential milestone payments associated with a license agreement with Bioprojet, of between \$40.0 million and \$142.0 million. We have financed our operations to date with proceeds from the sale of preferred convertible stock and debt financings. We are now generating WAKIX sales, which we expect to reduce our negative cash flows over the next 12 months.

We may need to raise additional capital in order to continue to fund operations, including milestone obligations under the Bioprojet License Agreement. We believe we will be able to obtain additional capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on acceptable terms. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

Accordingly, these factors raise substantial doubt about our ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

For the three months ended March 31, 2020 and 2019, and for the years ended December 31, 2019 and 2018, we did not have any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of some of our costs incurred under our Services Agreement and which costs are charged to research and development and general and administrative expense. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we

apply those principles. While our accounting policies are more fully described in Note 3 to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Revenue Recognition

Effective January 1, 2019, we adopted ASC 606, Revenue from Contracts with Customers (ASC 606), or ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We have determined that the delivery of our product to our customer constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered to be fulfilment activities and are not considered to be a separate performance obligation. We have assessed the existence of a significant financing component in the agreements with our customers. The trade payment terms with our customers do not exceed one year and therefore, no amount of consideration has been allocated as a financing component. Taxes collected related to product sales are remitted to governmental authorities and are excluded from revenue.

Product Sales, Net

We began commercial sales of WAKIX in November 2019. We sell WAKIX to our customers (a limited number of specialty distributors) that, in turn, distribute WAKIX to patients.

We recognize revenue on sales of WAKIX when the customer obtains control of the product, which occurs at a point in time, typically upon delivery. Product revenues are recorded at the product's wholesale acquisition costs, net of applicable reserves for variable consideration that are offered within contracts between us and our customers, payors, and other indirect customers relating to the sale of WAKIX. Components of variable consideration include government and commercial contracts, product returns, commercial co-payment assistance program transactions, and distribution service fees. These deductions, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as a current liability or reduction of receivables, based on the expected value method and a range of outcomes and are probability weighted in accordance with ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under contracts will not occur in a future period. Our analyses contemplate the application of the constraint in accordance with ASC 606. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Government Contracts

We have entered into contracts (i) to participate in the Medicaid Drug Rebate Program and the Medicare Part D program, and (ii) to sell to the U.S. Department of Veterans Affairs, 340b entities and other government agencies, or Government Payors, so that WAKIX will be eligible for purchase by, in partial or full reimbursement from, such Government Payors. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accounts payable or accrued expenses. For Medicare Part D, we estimate the number of patients in the prescription drug coverage gap for whom we will owe a payment under the Medicare Part D program.

We estimate the rebates that we will provide to Government Payors for those programs that require rebates. These rebate estimates are based upon (i) the government-mandated discounts applicable to government-funded programs, (ii) information obtained from its customers and (iii) information obtained from other third parties regarding the payor mix for WAKIX. The liability for these rebates consists of estimates of claims for the current year and estimated future claims that will be made for product shipments that have been recognized as revenue but remain in the distribution channel inventories at the end of each reporting period.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed and some require advanced payments. We make estimates of our accrued expenses of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services on our behalf and any clinical trials;
- investigative sites or other providers in connection with studies and any clinical trials;
- vendors in connections with the preparation of our NDA file, market and patient awareness programs, website development, market research and analysis and medical education;
- · vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses for services rendered on our estimates of the services received and efforts expended pursuant to quotes, contracts and communicating with our vendors. The financial terms of these agreement are subject to negotiation, vary from contract to contract and may result in uneven payments. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid or accrued expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We recognize stock-based compensation expense related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

We recognize stock-based compensation expense related to stock options granted to non-employees issued in exchange for services based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model; however, the fair value of the stock options granted to non-employees is remeasured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or a reduction in previously recognized expense, respectively, during the period the related services are rendered.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of share-based awards. These assumptions include:

Expected term. Our expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). For stock-based awards granted to non-employees, the expected term represents the contractual term of the award.

Common stock price. Our board of directors estimates the fair value of our common stock. Given the absence of a public trading market for our common stock, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately Held-Company Equity Securities Issued as Compensation, our board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine its best estimate of the fair value of our common stock, as further described below under "—Common Stock Valuations."

Expected volatility. Prior to this offering, we were a privately held company and did not have any trading history for our common stock and the expected volatility was estimated using weighted-average measures of implied volatility and the historical volatility of our peer group of companies for a period equal to the expected life of the stock options. Our peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-free interest rate. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock options.

Expected dividend. We have never paid, and do not anticipate paying, cash dividends on our common stock. Therefore, the expected dividend yield was assumed to be zero.

The following table reflects the weighted average assumptions used to estimate the fair value of options granted during the periods presented.

	2020	2019	2018
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	95.80%	95.30 - 99.30%	112.00%
Risk-free interest rate	0.51%	1.60 - 2.59%	2.39%
Lack of marketability discount	20.48%	26.00 - 31.00%	43.00%
Expected term (years)	6.50	6.50	6.50

Common Stock Valuations

Historically, for all periods prior to this initial public offering, the fair values of the shares of common stock underlying our stock-based awards were determined on each grant date by our board of directors. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; our actual operating results and financial performance; the progress of our commercialization and research and development efforts; conditions in the industry and economy in general; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions; equity market conditions affecting comparable public companies; the lack of marketability of our common stock and the results of independent third party valuations. Our board of directors also took into consideration the valuations of our common stock that were prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

For our valuations performed as of, and prior to, December 31, 2018, we used the Option Pricing Model Backsolve method to estimate the fair value of our common stock. In an option pricing method, or OPM, framework, the backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. For our February 13, 2019 valuation, we used an income-based approach of a Discounted Cash Flow, or DCF, method to estimate the fair value of our common stock. The DCF method is based upon the theory that the value of a business is equal to the present value of its projected future cash flows. For our valuations performed August 14, 2019, and thereafter, we used a combination of both, Backsolve and DCF, to estimate the fair value of our common stock. Furthermore, as of each of the valuation dates and even being a late stage development company, the future liquidity events were difficult to forecast. We applied a discount for lack of marketability to account for a lack of access to an active public market.

Our common stock valuations as of March 31, 2020, December 31, 2019, August 14, 2019, February 13, 2019, and December 31, 2018 of \$1.67, \$0.87, \$0.81, \$0.65 and \$0.52 respectively, per share. All option grants prior to March 31, 2020 were made above such valuations at an exercise price of \$1.00 per share and all options subsequent to March 31, 2020 have an exercise price equal to the valuation.

After the closing of this offering, our board of directors will determine the fair value of each common share underlying share-based awards based on the closing price of our common shares as reported on the primary stock exchange on which our common stock is traded.

Based upon the initial public offering price of \$ purchase our common shares as of , 2020 was \$

per common share, the aggregate intrinsic value of outstanding options to million, all of which are related to unvested options.

Options Granted

The following table sets forth by grant date the number of shares of common stock subject to options granted from January 1, 2019 through the date of this prospectus, the per share exercise price of the options, the per share fair value of the shares of common stock on each grant date and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options		Fair Value per Share on Grant Date		Per Share Estimated Fair Value of Options	
January 7, 2019	330,000	\$	1.00	\$	0.40	\$	132,000
January 28, 2019	100,000	\$	1.00	\$	0.40	\$	40,000
February 11, 2019	20,000	\$	1.00	\$	0.40	\$	8,000
March 11, 2019	50,000	\$	1.00	\$	0.50	\$	25,000
March 25, 2019	70,000	\$	1.00	\$	0.50	\$	35,000
April 8, 2019	40,000	\$	1.00	\$	0.50	\$	20,000
April 15, 2019	310,000	\$	1.00	\$	0.50	\$	155,000
April 22, 2019	245,000	\$	1.00	\$	0.50	\$	122,500
April 29, 2019	180,000	\$	1.00	\$	0.50	\$	90,000
May 13, 2019	40,000	\$	1.00	\$	0.50	\$	20,000
May 20, 2019	110,000	\$	1.00	\$	0.50	\$	55,000
June 17, 2019	990,000	\$	1.00	\$	0.50	\$	495,000
June 24, 2019	40,000	\$	1.00	\$	0.50	\$	20,000
July 1, 2019	430,000	\$	1.00	\$	0.50	\$	215,000
August 5, 2019	70,000	\$	1.00	\$	0.50	\$	35,000
August 26, 2019	5,000	\$	1.00	\$	0.62	\$	3,100
September 30, 2019	30,000	\$	1.00	\$	0.62	\$	18,600
October 21, 2019	30,000	\$	1.00	\$	0.62	\$	18,600
October 28, 2019	300,000	\$	1.00	\$	0.62	\$	186,000
January 1, 2020	125,000	\$	1.00	\$	0.69	\$	86,250
January 13, 2020	5,000	\$	1.00	\$	0.69	\$	3,450
January 22, 2020	20,000	\$	1.00	\$	0.69	\$	13,800
February 26, 2020	30,000	\$	1.00	\$	0.69	\$	20,700
March 1, 2020	25,000	\$	1.00	\$	0.69	\$	17,250
March 2, 2020	20,000	\$	1.00	\$	0.69	\$	13,800
March 4, 2020	943,485	\$	1.00	\$	0.69	\$	651,005
March 16, 2020	85,000	\$	1.00	\$	0.69	\$	58,650
March 23, 2020	30,000	\$	1.00	\$	0.69	\$	20,700

Stock Appreciation Rights Granted

The following table sets forth by grant date the number of shares of common stock subject to stock appreciation rights, or SARs, granted from January 1, 2019 through the date of this prospectus,

the per share base price of the SARs, the per share fair value of the shares of common stock on each grant date and the per share estimated fair value of the SARs:

Grant Date	Number of Shares Subject to SARs Granted	Per Share Base Price of SARs		Fair Value per Share on Grant Date		Per Share Estimated Fair Value of SARs	
January 7, 2019	330,000	\$	1.00	\$	0.40	\$	132,000
April 22, 2019	50,000	\$	1.00	\$	0.50	\$	25,000

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Deferred tax assets may be reduced by a valuation allowance if, based on all available evidence, it is more likely than not that some portion or all of the deferred income tax assets will not be realized. Management judgment is required in determining the period in which a reversal of a valuation allowance should occur. We are required to consider all available evidence, both positive and negative, such as historical levels of income and future forecasts of taxable income among other items, in determining whether a full or partial release of its valuation allowance is required. Our accounting for deferred tax consequences represents the best estimate of those future events. We present deferred income taxes on the Consolidated Balance Sheet on a jurisdictional basis as either a net noncurrent asset or liability.

We recognize the effect of income tax positions only if those positions are more likely than not sustainable, based solely on its technical merits and consideration of the relevant taxing authority's widely understood administrative practices and precedents. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which a change in judgment occurs. At March 31, 2020 and 2019 and December 31, 2019 and 2018, we did not have any unrecognized uncertain tax positions. Our policy is to include any interest and penalties as a component of income tax expense.

Recent Accounting Pronouncements

See Note 3 to our financial statements included elsewhere in this prospectus for more information.

The JOBS Act

We are an "emerging growth company", or EGC, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the

extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. If we were to subsequently elect instead to comply with these public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We will remain an EGC until the earliest of (i) the last day of our fiscal year (a) following the fifth anniversary of the completing of this offering, (b) in which we have total annual gross revenues of at least \$1.07 billion or (ii) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities over a three-year period.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2020, our cash and cash equivalents consisted of cash and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of March 31, 2020, we had \$200.0 million in borrowings outstanding. The term loan bears interest at an interest rate of the greater of (a) LIBOR or (b) 2.00% per annum, plus 11.00% per annum. Based on the \$200.0 million of principal outstanding as of March 31, 2020, an immediate 10% change in the Prime Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

Foreign Currency Fluctuation Risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation Fluctuation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations for the three months ending March 31, 2020 and 2019 and for the years ending December 31, 2019 and 2018.

BUSINESS

Overview

We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients with rare neurological disorders living with unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action, or MOA, specifically designed to increase histamine signaling in the brain by binding to H₃ receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of our lead indication, excessive daytime sleepiness, or EDS, in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance. We plan to pursue label expansion for WAKIX in narcolepsy in pediatric patients and engage with the FDA in pursuit of pediatric exclusivity. We currently expect to initiate a Phase 3 clinical trial in pediatric patients in the second half of 2021 in pursuit of indications for both EDS and cataplexy. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication WAKIX. We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through H₃ receptors and histamine signaling. We are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome, or PWS, and myotonic dystrophy, or MD. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020, with topline results expected in the first half of 2022. We are also planning to commence a Phase 2 clinical trial in adult patients with MD in the first half of 2021, with topline results expected in the second half of 2022, subject to receiving authorization to proceed under an Investigational New Drug application, or IND. Beyond these indications, we intend to further explore pitolisant in other rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.

Pitolisant was developed by Bioprojet Société Civile de Recherche, or Bioprojet, and approved by the European Medicines Agency, or EMA, in 2016 for the treatment of narcolepsy in adult patients with or without cataplexy. We acquired an exclusive license to develop, manufacture and commercialize pitolisant in the United States pursuant to our license agreement with Bioprojet, or the Bioprojet License Agreement, in July 2017. See "—Strategic Agreement—License and Commercialization Agreement with Bioprojet" for further information regarding the Bioprojet License Agreement. Pitolisant was granted Orphan Drug Designation for the treatment of narcolepsy by the FDA in 2010. It received Breakthrough Therapy designation from the FDA for the treatment of cataplexy in patients with narcolepsy and Fast Track status for the treatment of EDS and cataplexy in patients with narcolepsy in April 2018.

Narcolepsy Market Overview

Narcolepsy is a rare, chronic and debilitating neurologic disorder of sleep-wake state instability that is estimated to affect approximately 165,000 Americans, with fewer than 50% diagnosed. Narcolepsy is characterized by EDS, which is present in all patients with narcolepsy and is the primary reason why patients seek treatment. EDS is the inability to stay awake or alert throughout the day, including an irrepressible need for sleep, with lapses into drowsiness or sleep, which has a significant impact on a patient's ability to function. Additional symptoms of narcolepsy may include cataplexy (which is characterized by sudden and transient episodes of muscle weakness accompanied by full conscious awareness), hallucinations, sleep paralysis and disrupted nighttime sleep. In most patients, narcolepsy is caused by the loss of hypocretin, a neuropeptide in the brain that, along with histamine,

works to support sleep-wake state stability. This disorder affects men and women equally, with typical symptom onset in adolescence or young adulthood; however, it can take up to a decade after onset of symptoms to be properly diagnosed. The U.S. narcolepsy market had an approximate net sales value of \$1.8 billion in 2019. The market is expected to continue to grow based on several factors, including, but not limited to, the introduction of new innovative therapies that offer novel mechanisms of action resulting in improved safety/tolerability profiles while delivering clinically meaningful efficacy, additional investment in education, increased rates of diagnosis, and population growth.

Prior to the approval of WAKIX, there were six approved medications to treat patients with narcolepsy, all of which are scheduled as controlled substances. These include Xyrem (sodium oxybate), Provigil (modafinil), Nuvigil (armodafinil), Ritalin (methylphenidate), Adderall (amphetamine salts) and, Sunosi (solriamfetol). These approved drugs are prescribed in accordance with their individual labels for indications covering narcolepsy, cataplexy and/or EDS related to narcolepsy, and have demonstrated the ability to improve the lives of the patients suffering from these indications. Other prescription drugs are used off-label for the treatment of either EDS or cataplexy in patients with narcolepsy, including stimulants for EDS and antidepressants for cataplexy. Despite the benefits provided by the available medications, according to the American Academy of Sleep Medicine, or AASM, traditional stimulants, wake-promoting agents and sodium oxybate, at best, provide only moderate improvement in narcolepsy symptoms and side effects may limit their use. Some of the current therapies have significant side effects (such as increased heart rate and blood pressure) and boxed warnings due to the risk of respiratory depression, abuse and dependence. These therapies also have the potential for rebound and withdrawal symptoms. According to the 2007 AASM treatment guidelines, medications for narcolepsy, at best, provided only moderate improvement in narcolepsy symptoms and side effects may limit their use. The Voice of the Patient report from the FDA's patient-focused drug development initiative, published in 2014, concluded that, based on the overall benefit-risk assessment of current medications, there is a continued need for additional effective and tolerable treatment options for patients with narcolepsy. In a retrospective electronic chart review conducted on our behalf from June 2011 to December 2018, over 75% (73 out of 97 respondents) of patients with narcolepsy reported at least one residual symptom while on their current treatment. In a third party survey that we commissioned prior to the commercialization of WAKIX, of the 200 patients with narcolepsy who were surveyed, 86% (173 out of 200 respondents) of patients reported narcolepsy is a life changing disorder and 93% (157 out of 169 respondents) expressed frustration with current treatment options, while 31 patients were not on treatment and, as such, did not provide a response to this question. The main drivers of patients' dissatisfaction were side effects and tolerability, loss of efficacy over time and concerns about abuse and dependence with current therapies. In 2019, two new therapies for narcolepsy, including WAKIX, were approved by the FDA, which represent the first new therapies for narcolepsy patients in the United States since 2007.

In market research sponsored by us prior to the commercial release of WAKIX, both patients and healthcare professionals, or HCPs, expressed frustration and dissatisfaction with then-existing therapies, reflecting current unmet medical needs. These unmet needs included, in order of importance, the availability of: (i) non-scheduled treatment options, (ii) more tolerable treatment regimens, (iii) more effective treatment options, (iv) novel MOAs beyond currently available therapies and (v) once-daily treatment options. Based on our market research, we believe the most significant unmet need identified was the availability of non-scheduled treatment options. Other than WAKIX, all drugs approved by the FDA for the treatment of narcolepsy, including stimulants, are scheduled as controlled substances by the DEA. Controlled substances have the potential for abuse, misuse, diversion. In addition, these products also have the potential for the development of tolerance and withdrawal symptoms. Despite their inherent drawbacks, due to the limited number of treatment options, stimulants have historically been a primary treatment for people with narcolepsy. In addition to having the potential for abuse, all of the treatments approved for narcolepsy, except WAKIX, require a Risk Evaluation and Mitigation Strategy, or REMS, program, which is required by the FDA for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

Our Solution

WAKIX (pitolisant) represents a novel approach to narcolepsy treatment. We believe that WAKIX offers a meaningfully differentiated product profile over current treatment options for the following reasons:

- *First-in-class molecule with a novel MOA*. WAKIX is the only selective H₃ receptor antagonist/inverse agonist approved by the FDA for the treatment of EDS in adult patients with narcolepsy and is the only narcolepsy treatment that works primarily through histamine, a major wake-promoting neurotransmitter. Pitolisant is thought to work by regulating histamine, such that it activates wake-promoting neurons and inhibits sleep promoting neurons, which helps to stabilize states of sleep and wakefulness. We believe that these novel characteristics differentiate it from other narcolepsy treatments.
- First-and-only non-scheduled treatment for narcolepsy. WAKIX is the first-and-only FDA-approved treatment for narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration, or the DEA. We believe one of the most significant unmet needs is the availability of non-scheduled treatment options. In a clinical trial, pitolisant demonstrated statistically significantly lower drug liking compared to phentermine (a Schedule IV stimulant), consistent with its lack of abuse potential.
- WAKIX is not a stimulant. Stimulants are one of the most commonly prescribed treatments for patients with narcolepsy. Unlike stimulants, WAKIX has shown no evidence for the development of drug tolerance or withdrawal symptoms. Therefore, there is no need for patients to temporarily stop the medication to reset efficacy. In addition, unlike stimulants, WAKIX does not increase dopamine levels in the brain's reward center, which contributes to its lack of abuse potential. According to the National Sleep Foundation, stimulants have the potential for abuse, so their use must be considered carefully by patients and HCPs. WAKIX gives patients and HCPs a new therapeutic option.
- WAKIX can be used as monotherapy or administered concomitantly with other narcolepsy treatments. Narcolepsy is a
 difficult disorder to manage and the majority of narcolepsy patients often require multiple medications to treat their symptoms.
 WAKIX was studied in combination with each of modafinil and sodium oxybate (two common treatments for narcolepsy) and
 demonstrated no effect on the pharmacokinetic, or PK, profile of either treatment, and neither treatment had a clinically relevant
 effect on the PK profile of WAKIX. We believe the ability of WAKIX to be taken as monotherapy or concomitantly with other
 narcolepsy medications affords HCPs the flexibility to better manage their patients with narcolepsy.
- WAKIX is a once-daily oral tablet administered in the morning upon wakening. Patients have identified a need for treatment options that are easier to take and are dosed less frequently. We believe that once-daily dosing with WAKIX addresses this need and may help improve patient compliance with treatment.

Our Strategy

Our goal is to become a leading pharmaceutical company dedicated to developing and commercializing novel treatment options for patients with rare neurological disorders living with unmet medical needs, beginning with a focus on narcolepsy. The key elements of our strategy are to:

Commercialize WAKIX in the United States. We have assembled a team of approximately 150 professionals that possess
comprehensive life sciences experience. We have also established a robust company infrastructure to execute on our core
business and growth

strategies. This team includes over 70 dedicated and experienced sales professionals who call on the approximately 8,000 HCPs who treat approximately 90% of narcolepsy patients in the United States. In November 2019, we launched commercial sales of WAKIX in the United States.

- Expand WAKIX Label in Narcolepsy. Building upon an EDS indication in adult patients with narcolepsy, we expect to initiate a Phase 3 clinical trial in pediatric narcolepsy patients in the second half of 2021 with the goal of gaining a pediatric indication for both EDS and cataplexy. We also plan to engage with the FDA to pursue pediatric exclusivity. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication.
- Pursue New Indications Beyond Narcolepsy. We believe that pitolisant's novel MOA has therapeutic potential in several other rare neurological disorder patient populations. We submitted an IND in October 2019 and received acknowledgement from the FDA that the proposed clinical investigation may proceed. We subsequently completed a Phase 1 PK clinical trial in pediatric patients with PWS in the fourth quarter of 2019, and initiated a long-term, open-label safety trial in these patients. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020. Topline results from this clinical trial are expected in the first half of 2022. For patients with MD, we are planning to evaluate pitolisant for the treatment of EDS and other key symptoms in a Phase 2 clinical trial targeted to commence first half of 2021, subject to receiving authorization to proceed under an IND. Topline results from this clinical trial are expected in the second half of 2022. We also plan to explore pitolisant's potential as a treatment for EDS and related symptoms in other rare neurologic disorders, including those in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.
- Explore Expansion of our Product Portfolio. We plan to explore obtaining additional licensing rights from Bioprojet to expand into certain international markets with WAKIX. As we continue our commercial growth and develop a global footprint, we will assess in-licensing or acquiring complementary rights, assets or product candidates that allow us to leverage our existing infrastructure and expand within our strategic areas of focus.

Early Launch Metrics

As of May 31, 2020, over 1,600 unique HCPs (out of a total of approximately 8,000 HCPs who treat approximately 90% of diagnosed narcolepsy patients) have prescribed WAKIX since it became available in November 2019 to a total of over 2,400 unique patients (out of the approximately 42,000 diagnosed and treated narcolepsy patients in the United States). We have secured formulary access for over 161 million lives, which represents 68% of our target covered lives, which we define as a group of certain public and private payors that account for approximately 80% of all covered lives in the United States. For the three months ended March 31, 2020, net sales of WAKIX were \$19.8 million.

Our History and Leadership Team

Our operating subsidiary, Harmony Biosciences, LLC, was formed in May 2017. We were formed as a Delaware limited liability company in July 2017 and converted to a Delaware corporation in September 2017. We concurrently acquired the U.S. rights to develop and commercialize pitolisant from Bioprojet. In February 2020, we changed our name to Harmony Biosciences Holdings, Inc. Since inception, we have raised approximately \$345 million in equity financing from healthcare investors including Paragon Biosciences, LLC, venBio Partners, Novo Holdings A/S, Valor Equity Partners, Vivo

Capital and HBM Healthcare Investments, or their respective affiliates. We have assembled an experienced leadership team with a track record of developing and commercializing products to treat rare neurological disorders. We believe that the clinical development, regulatory, commercial and operational expertise of our executive and senior leadership team will be essential as we execute on our strategy of becoming a leading pharmaceutical company focused on developing and commercializing innovative therapies for the treatment of rare neurological disorders while delivering significant value to both patients and shareholders.

Our management team has held senior positions at leading pharmaceutical companies, including Cephalon, Inc., or Cephalon, Teva Pharmaceutical Industries Ltd., or Teva, Merck & Co., Inc., or Merck, Wyeth, LLC and ViroPharma Incorporated, or ViroPharma, among others, and possesses substantial experience and expertise in developing and commercializing products for rare neurological disorders, including narcolepsy and other sleep disorders.

John C. Jacobs, our President and Chief Executive Officer, has held a variety of senior leadership roles of increasing responsibility throughout his career including roles in marketing, commercial, operations and general management in both U.S. and global markets. Prior to Harmony, Mr. Jacobs held roles as General Manager of Teva's branded business in Canada and led North American Commercial Operations for Teva. Jeffrey Dierks, our Chief Commercial Officer, formerly Vice President of Marketing at Harmony Biosciences and Senior Director U.S. Pain Care and Sleep Disorders and Migraine Marketing at Teva, has over 20 years of commercial leadership experience with demonstrated success in leading product launches. Jeffrey Dayno, MD, our Chief Medical Officer, formerly Chief Medical Officer at Egalet Corporation, is a neurologist with 10 years of experience in clinical and academic medicine followed by over 20 years of experience in research and development leadership roles at Merck, Cephalon and ViroPharma.

Overview of Development Pipeline

Label Expansion

We are actively working on label expansion for WAKIX in narcolepsy, including label expansion for the treatment of pediatric patients suffering from narcolepsy. Approximately 3,600 of the diagnosed narcolepsy patients in the United States are pediatric patients 19 years of age or under. We believe that these pediatric patients could benefit from new treatment options. Accordingly, we currently expect to initiate a Phase 3 clinical trial in the second half of 2021 for indications for both EDS and cataplexy in pediatric patients. Topline results from this clinical trial are expected in the first half of 2023. We also intend to work with the FDA toward obtaining pediatric exclusivity for WAKIX.

In addition, the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We are evaluating our options regarding the approach to take with the FDA to expand the label for WAKIX for cataplexy, despite the initial FDA decision to not grant this indication. While all patients with narcolepsy have the primary symptom of EDS, for which WAKIX is approved in adult patients, it is estimated that 60% to 70% of those diagnosed with narcolepsy and treated also experience cataplexy, representing approximately 25,000 to 30,000 patients in the United States. We believe that an additional indication for cataplexy in adult patients would strengthen the product profile for WAKIX and enable access to WAKIX for adult patients suffering from both EDS and cataplexy associated with narcolepsy. Depending on the regulatory path we pursue for approval, we could obtain the adult cataplexy indication as early as the second half of 2020, if ever. If we conduct an additional clinical trial related to a cataplexy indication in adult patients with narcolepsy, we anticipate that any such clinical trial will be funded by Bioprojet pursuant to Bioprojet License Agreement. If we are granted approval for a cataplexy indication with or without the need for an additional trial, we will

need to make a milestone payment to Bioprojet in accordance with the Bioprojet License Agreement. If that outcome should occur, we may use a portion of the proceeds of this offering to fund such milestone payment. See "Use of Proceeds" and "—Strategic Agreement—License and Commercialization Agreement with Bioprojet."

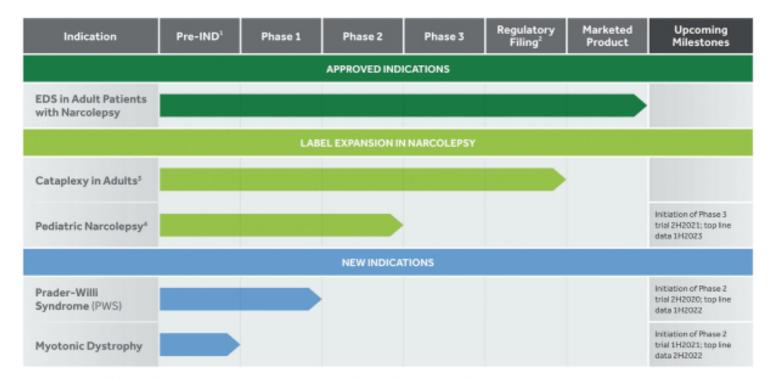
Additional Indications

We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through the H3 receptor and histamine signaling. We plan to explore the potential benefit of pitolisant in additional rare neurological indications beyond narcolepsy, initially focusing on the treatment of EDS associated with PWS and MD. For these potential new indications, we do not anticipate being required to conduct additional preclinical studies or studies enabling an Investigational New Drug application, or IND, beyond those studies that are already included in the NDA for WAKIX, which were referenced when the IND for PWS was opened. Similarly, we intend to reference these studies when the IND for MD is submitted.

PWS is a rare genetic disorder caused by a loss of function of specific genes on chromosome 15 resulting in hypothalamic dysfunction. The hypothalamus controls both sleep-wake states and hunger-satiety. Therefore, two of the main symptoms in patients with PWS are EDS and insatiable hunger, or hyperphagia. Other consequences of PWS include low muscle tone, short stature, behavioral problems and cognitive impairment. It is estimated that approximately 15,000 to 20,000 people in the United States suffer from PWS, and over half of those suffering from PWS also have reported or experienced EDS. We opened an IND and completed a Phase 1 PK clinical trial in pediatric patients with PWS in the fourth quarter of 2019, and initiated a long-term, open-label safety study in these patients. We intend to commence a Phase 2 clinical trial in patients with PWS in the second half of 2020. Topline results from this clinical trial are expected in the first half of 2022.

MD is a rare, multi-system genetic disease that affects the neuromuscular system as well as several other systems. It is inherited in an autosomal dominant pattern and there are two main types: type 1, or DM1, and type 2, or DM2. The underlying cause of DM1 is a mutation in the myotonic dystrophy protein kinase, or DMPK, gene on chromosome 19. DM1 is the most common form of adult-onset muscular dystrophy and affects as many as 140,000 patients in the United States. EDS and fatigue are hallmark clinical characteristics in the majority of patients with DM1 and are referred to as the most frequent non-muscular symptoms in patients with DM1. Cognitive impairment is also a prominent symptom in patients with DM1 and all of these symptoms are thought to be mediated through H3 receptors and histaminergic pathways located throughout the central nervous system, or CNS. DM2 is not as common as DM1 with an estimated prevalence of between 3,000 and 29,000 patients in the United States. The underlying cause of DM2 is a mutation in the CCHC-Type Zinc Finger Nucleic Acid Binding Protein, or CBNP, gene on chromosome 3. Patients with DM1 and DM2 share similar phenotypes but disease onset is later in patients with DM2 and symptoms tend to be milder. A pre-IND meeting was scheduled with the FDA for March 2020 to discuss a trial in DM1 patients, but was cancelled because we deemed the preliminary meeting comments adequate to advance the program forward. We are now planning to include both patients with DM1 and patients with DM2 in our study, subject to feedback from FDA, and we anticipate commencing a Phase 2 clinical trial in adult patients with MD in the first half of 2021. Topline results from this clinical trial are expected in the second half of 2022.

Overview of Development Pipeline



- For each potential new indication, we do not anticipate being required to conduct additional preclinical studies or studies enabling an IND
 beyond those studies that are already included in the New Drug Application for WAKDX. Additional preclinical studies were not required to open the IND for PWS.
- 2. Includes New Drug Applications and supplemental New Drug Applications.
- 3. We received a Complete Response Letter for cataplexy in August 2019; the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We are evaluating our options regarding the approach to take in pursuit of this indication.
- Current trial being conducted by Bioprojet. We plan to initiate a Phase 3 clinical trial in 2H2021 in pursuit of pediatric indications for both EDS and cataplexy as well as pediatric exclusivity.

Beyond the target indications listed above, we intend to further explore pitolisant in other rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.

Our Commercialization Strategy

We launched WAKIX into the narcolepsy market in November 2019 and are engaging with HCPs, patients and payors through the focused commercialization strategy outlined below to optimize adoption of WAKIX in the marketplace:

- HCP Awareness and Adoption: To facilitate HCP awareness and adoption of WAKIX, we have deployed our dedicated, in-house, over 70-person sales team to educate a defined prescriber base of approximately 8,000 HCPs comprised of neurologists, pulmonologists, sleep specialists, psychiatrists and high-prescribing primary care physicians who specialize in or focus on sleep disorders. We believe these HCPs diagnose and treat approximately 90% of the narcolepsy patients in the United States. We began our commercial HCP outreach in August 2019 following FDA approval of WAKIX for the treatment of EDS in adult patients with narcolepsy.
- Patient Awareness: It is estimated that narcolepsy affects approximately 165,000 Americans with fewer than 50% diagnosed.
 Of those living with narcolepsy in the United States, it is estimated that fewer than 45,000 are on narcolepsy medications, which we believe indicates a significant unmet medical need. To drive patient awareness of WAKIX and its differentiated product profile, we have been communicating with the narcolepsy patient community and providing them with educational materials and information on WAKIX.

• **Payor Coverage**: Recognizing the importance of payor coverage, our field market access team has been engaging with national and regional payors over the past two years to educate them on the clinical data and value proposition of WAKIX. Through May 31, 2020, we have secured formulary access covering approximately 161 million lives.

We believe the differentiating attributes of WAKIX that will facilitate awareness, adoption, and coverage include: (i) it is a first-in-class molecule with a novel MOA, (ii) it is the first-and-only non-scheduled treatment approved for narcolepsy, (iii) it is not a stimulant, (iv) it has broad clinical utility because it can be used as monotherapy or administered concomitantly with other narcolepsy treatments, and (v) it is a once-daily oral tablet administered in the morning upon wakening.

Clinical Development of WAKIX (pitolisant)

Overview

The strategy behind the clinical development of pitolisant is based on its MOA, which is thought to work by regulating histamine transmission. Pitolisant is a first-in-class molecule with a novel MOA, acting as a potent and highly selective antagonist/inverse agonist of the H₃ receptor. It activates histaminergic neurons in the brain, a neuronal system involved in the maintenance of wakefulness, attention, vigilance and cognition. Pitolisant binds to H₃ receptors on presynaptic neurons and blocks the normal negative feedback mechanism for histamine release, resulting in increased release of this wake-promoting neurotransmitter. It also functions as an inverse agonist, resulting in enhanced histamine synthesis and release from presynaptic neurons. Increased histamine available in the synapse binds to postsynaptic H₁ receptors, activating postsynaptic neurons, which stimulate wake-promoting brain regions and inhibit sleep-promoting regions of the brain.

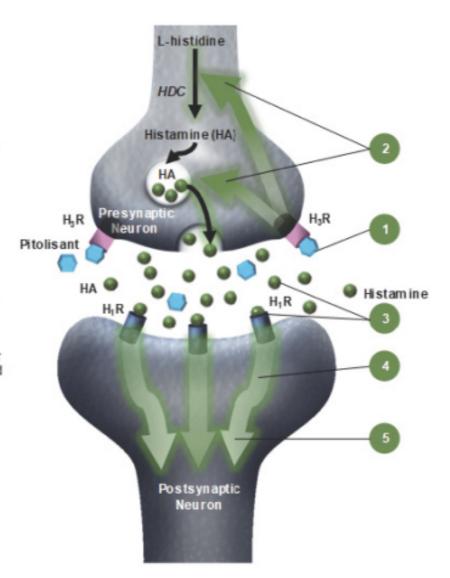
Pitolisant also stimulates the release of other wake-promoting neurotransmitters (dopamine, norepinephrine, serotonin and acetylcholine) via H₃ heteroreceptors within those neuronal systems. Importantly, pitolisant does not increase dopamine levels in the striatum, including the nucleus accumbens, which is the brain's reward center where an increase in dopamine levels is correlated with abuse potential. This feature of pitolisant's MOA, along with primarily working through the histaminergic system, are two of the aspects that differentiate pitolisant from all other currently approved treatments for narcolepsy.

WAKIX® (pitolisant) Mechanism of Action

Pitolisant is a histamine H₃-receptor antagonist / inverse agonist that enhances the activity of histaminergic neurons in the brain

- Pitclisant binds to presynaptic H₃ autoreceptors, which blocks histamine binding to these receptors and increases histamine release from presynaptic neurons
- Acting as an inverse agonist, pitolisant initiates increased histamine synthesis and release from vesicles into the synapse
- This increased histamine in the synapse is then available to bind to excitatory postsynaptic H₁ receptors
- Increased histamine binding at H₁ receptors results in an increase in neuronal firing of postsynaptic neurons
- Increased firing of histamine neurons further activates wake-associated brain regions and further inhibits non-REM and REM sleepassociated brain regions

HA = Histamine HDC = L-histidine decarboxylase H₃R = Histamine 3 Receptor H₄R = Histamine 1 Receptor



The safety profile of pitolisant is based on pooled safety data from 22 Phase 2/3 clinical trials conducted by Bioprojet, eight of which were in patients with narcolepsy and 14 of which were in other indications. These trials included 1,513 unique patients, of whom 1,043 received pitolisant in double-blind placebo-controlled studies, and others received pitolisant in single-blind or open-label trials. Three successful pivotal trials in narcolepsy, HARMONY 1, HARMONY 1bis, and HARMONY CTP, were completed in Europe by Bioprojet and served as the foundation for the approval of pitolisant by the EMA in 2016 for the treatment of narcolepsy in adults with or without cataplexy. Pitolisant was evaluated in a long-term safety and tolerability trial, HARMONY 3, which further supported the results observed in HARMONY 1, HARMONY 1bis, and HARMONY CTP. The data from these trials were submitted, along with a human abuse potential, or HAP, trial, to the FDA as part of the NDA for WAKIX (pitolisant), which the FDA approved on August 14, 2019 for the treatment of EDS in adult patients with narcolepsy. The table below provides an overview of the trial designs from these five clinical trials.

	Trial Design	Number of Patients; % with Cataplexy	Maximum Dose; % at that Dose	Primary Endpoint	Results
Harmony 1	Randomized, double-blind, placebo & active-controlled trial; patients with narcolepsy +/- cataplexy; 8 weeks in duration	N = 95 80%	35.6 mg; 61%	Change in Epworth Sleepiness Scale (ESS) score	ESS score change from baseline to final visit -6.0 for pitolisant compared to -2.9 for placebo (treatment effect -3.1; p=0.022)
Harmony 1bis	Randomized, double-blind, placebo & active-controlled trial; patients with narcolepsy +/- cataplexy; 8 weeks in duration	N = 166 75%	17.8 mg; 76%	Change in ESS score	ESS score change from baseline to final visit -5.0 for pitolisant compared to -2.8 for placebo (treatment effect -2.2; p=0.030)
HARMONY CTP	Randomized, double-blind, placebo-controlled trial; patients with narcolepsy and cataplexy; 7 weeks in duration	N = 106 100%	35.6 mg 65%	Change in Weekly Rate of Cataplexy (WRC)	Pitolisant demonstrated a significant reduction in the WRC compared to placebo (75% vs. 38%; p<0.0001)
HARMONY 3	Long-term, open-label, real- world trial; 31 year	N = 104 74%	35.6 mg 88%	Long-term safety	Safety / tolerability profile c/w that seen in the RCTs
Human Abuse Potential Study	Randomized, double-blind, active & placebo- controlled, 4-way crossover study	43 n/a	35.6 mg & 213.6 mg; Phentermine 60 mg (active control)	Maximum Drug Liking	Pitolisant demonstrated a statistically significant and clinically relevant reduction in drug liking compared to phentermine (p<0.0001)

RCTs = randomized controlled trials

Clinical Trial Highlights

The key findings from these clinical trials are as follows:

Pitolisant showed a statistically significant improvement in EDS in adult patients with narcolepsy in HARMONY 1 and HARMONY 1 bis compared to placebo. Specifically, the clinical trials demonstrated a statistically significant, and clinically relevant, improvement in EDS as measured by the Epworth Sleepiness Scale, or ESS, scores compared to placebo (p=0.022 in HARMONY 1 and p=0.030 in HARMONY 1 bis), supported by statistically significant improvement on the Maintenance of Wakefulness Test, or MWT.

- Pitolisant demonstrated a statistically significant reduction in measures of cataplexy in adult patients with narcolepsy in HARMONY CTP as compared to placebo. Reduction in the weekly rate of cataplexy in patients on pitolisant was 75% compared to a 38% reduction in the placebo group (p<0.0001). This finding was supported by a significant reduction in cataplexy (a secondary endpoint) in the HARMONY 1 trial of 62% in the pitolisant group compared to 8% in the placebo group (p=0.034). However, the FDA stated that the cataplexy data from the HARMONY 1 trial in the NDA did not provide substantial evidence of effectiveness with respect to cataplexy because the statistical analysis plan did not prospectively control for Type 1 error of the secondary endpoints, and the subgroup of patients with cataplexy was not identified prospectively. As a result, the FDA issued a complete response letter, or CRL, with respect to the cataplexy indication.</p>
- Pitolisant was generally well tolerated in clinical trials. In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (occurring in 35% of patients and at twice the rate of placebo) with the use of pitolisant were insomnia (6%), nausea (6%), and anxiety (5%). In these trials, 6 of the 152 patients (3.9%) who received pitolisant and 4 of the 114 patients (3.5%) who received placebo discontinued because of an adverse event.
- In the HARMONY 3 trial, a favorable long-term safety/tolerability profile for pitolisant out to one year was demonstrated; safety
 findings were similar to those seen in the randomized controlled trials, with no new safety signals identified.
 - In this open-label, long-term real-world trial, improvement in EDS (as measured by a reduction in ESS scores) and reduction in cataplexy (as measured by reduction in mean daily cataplexy episodes) was maintained out to twelve months
- In a clinical HAP trial, pitolisant demonstrated a statistically significantly lower maximum drug liking (primary endpoint), overall drug liking, and willingness to take drug again compared to phentermine (C-IV), with responses similar to placebo. No evidence of abuse potential based on clinical and preclinical data has been observed to date, and WAKIX was therefore approved without being scheduled as a controlled substance by the DEA.

HARMONY 1

Design

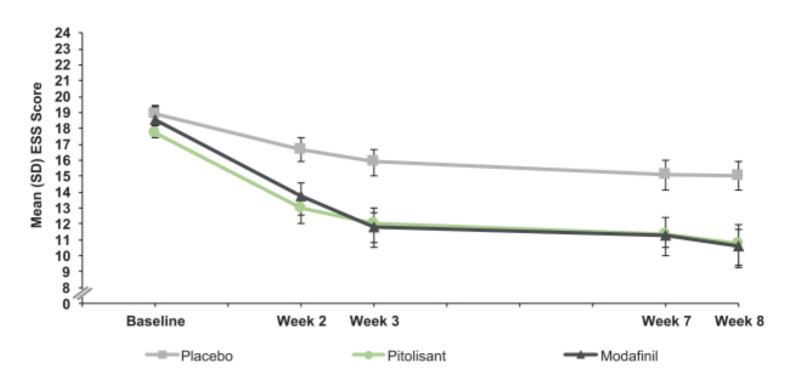
HARMONY 1 was a randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of pitolisant in adult patients with narcolepsy on improvement in EDS over an eight-week period. The trial was conducted in the EU, and consequently was designed to include both a placebo arm and an active comparator, modafinil, which was used in doses up to 400 mg/day. HARMONY 1 consisted of 95 patients and had flexible dosing during the first three weeks of the trial, followed by five weeks of stable dosing. The maximum dose of pitolisant in this dose-to-effect trial was 35.6 mg and only 61% of the patients were titrated to this dose for the stable dosing period. Approximately 80% of the patients had a history of cataplexy.

The primary endpoint in the trial was the ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo. ESS is a self-administered eight-item questionnaire scored 0 to 24 with lower scores corresponding to lower EDS. Secondary endpoints in HARMONY 1 included ESS responder rates, MWT (an objective measure of the ability to stay awake), the Sustained Attention to Response Task, or SART, reduction in cataplexy, Clinical Global Impression of Change, or CGI-C, for both EDS and cataplexy, the European Quality of Life Questionnaire, or the EQ-5D, and the Patient's Global Opinion on the Effect of Treatment Questionnaire. The main efficacy objective of the trial was to demonstrate superiority of pitolisant compared to placebo on the primary endpoint, while one of the secondary objectives was to explore the non-inferiority of pitolisant compared to modafinil on ESS score.

Efficacy Results

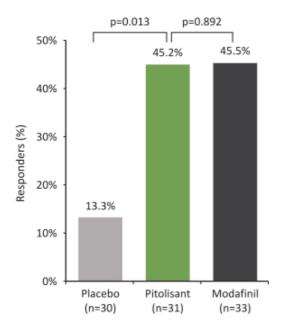
Pitolisant showed a significant reduction in the mean ESS score change from baseline to final visit at end of trial as compared to placebo (-6.0 versus -2.9, respectively) and between-group differences in ESS score were evident within the first two weeks of treatment. This resulted in a treatment effect (ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo) of -3.1, which was statistically significant for pitolisant versus placebo (p=0.022). The final adjusted ESS score for modafinil was -6.9 and, based on this score, pitolisant was not found to be non-inferior to modafinil (mean difference of 0.09, p=0.932) and the trial therefore did not meet this secondary efficacy objective. We believe there are several factors that contributed to this finding. First, 73% of the patients on modafinil in this trial were titrated up to a dose of 400 mg/day (the recommended dose of modafinil in the FDA-approved U.S. Prescribing Information, or USPI, is 200 mg/day) while only 61% of the patients on pitolisant were titrated to the maximum pitolisant dose of 35.6 mg/day (which is the maximum approved dose in the USPI), such that a greater number of patients in the modafinil arm received the maximum effective dose than those in the pitolisant arm, raising the possibility that those subjects in the pitolisant arm could have seen greater treatment effect had they been dosed at the maximum dose available. Second, the margin of non-inferiority for the difference in the ESS scores pre-specified in the statistical analysis plan was narrow (2 points), meaning that the change in ESS score adjusted for baseline compared between pitolisant and modafinil had to have a lower 95% CI of no less than -2 points to declare pitolisant non-inferior to modafinil. The lower bound of the 95% CI of the analysis fell just outside this margin (-2.11). According to literature, however, a clinically relevant difference on the ESS ranges from 2-3 points, such that the non-inferiority margins pre-specified under the statistical analysis plan may have been too narrow. Ultimately, however, the trial results comparing pitolisant and modafinil did not impact the FDA's findings that pitolisant was effective for improvement in EDS, and the FDA-approved label for WAKIX does not contain any data on modafinil.

Change in ESS Score Over Time

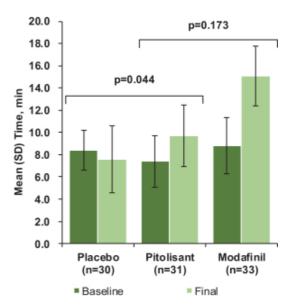


Regarding the secondary endpoints, ESS responder rates (a responder was defined as having a final ESS score £ 10) were significantly greater for those patients treated with pitolisant compared to those on placebo (45.2% vs. 13.3%, respectively; p=0.013). The responder rate for patients treated with modafinil was 45.5% and the difference compared to pitolisant was not statistically significant (p=0.892). On the MWT, pitolisant treatment improved performance when compared to placebo in a statistically significant manner (p=0.044), while improvement was not significantly different compared to modafinil (p=0.173).

Responders (Final ESS £ 10)



Change in MWT



With regard to other secondary endpoints, the overall pattern of response was that the findings for patients on both pitolisant and modafinil were superior to those on placebo while the responses were not statistically significantly different for pitolisant compared to modafinil. It should be noted that there was not a prospective plan to control for Type 1 error in this trial. The SART Total Score (a measure of attention) was significantly higher in the pitolisant group as compared to placebo (p=0.041), and while not significantly different from the modafinil group (p=0.363), the scores were similar (9.1 and 8.9 for pitolisant and modafinil, respectively). The CGI-C for EDS showed improvement in 56% of patients on placebo, 73% of patients on pitolisant, and 86% of patients on modafinil. Regarding the daily cataplexy rates endpoint, patients treated with pitolisant experienced a 62% reduction in the daily rate of cataplexy compared to a reduction of 8% in those on placebo (p=0.034); the difference between modafinil (25%) and placebo was not statistically significant (p=0.396). Responses on the CGI-C for cataplexy were consistent with this outcome, with 29%, 45%, and 35% of patients who experienced cataplexy during the trial reporting an improvement in their cataplexy symptoms in the placebo, pitolisant, and modafinil groups, respectively. Lastly, the Patient's Global Opinion on the Effect of Treatment Questionnaire recorded positive responses in 56% of patients in the placebo group, 81% of patients in the pitolisant group, and 86% of patients in the modafinil group.

Safety Results

Pitolisant was generally well tolerated in HARMONY 1. Sixty patients experienced a treatment emergent adverse event, or TEAE, during the trial: 61% in the pitolisant group, 60% in the placebo group, and 70% in the modafinil group. The most commonly reported TEAE in the pitolisant treatment group was headache, reported by 35% of the patients, compared to 20% in the placebo group. Other frequently reported TEAEs in the pitolisant treatment group were insomnia, nausea and weight increase (each reported by two patients, or 6%). There were five serious adverse events during HARMONY 1 and none were considered treatment-related (two in the pitolisant group, two in the modafinil group, and one in the placebo group). There were no deaths during the trial and no significant changes in laboratory values or hemodynamic parameters (heart rate and blood pressure) from baseline to final visit in any group.

HARMONY 1bis

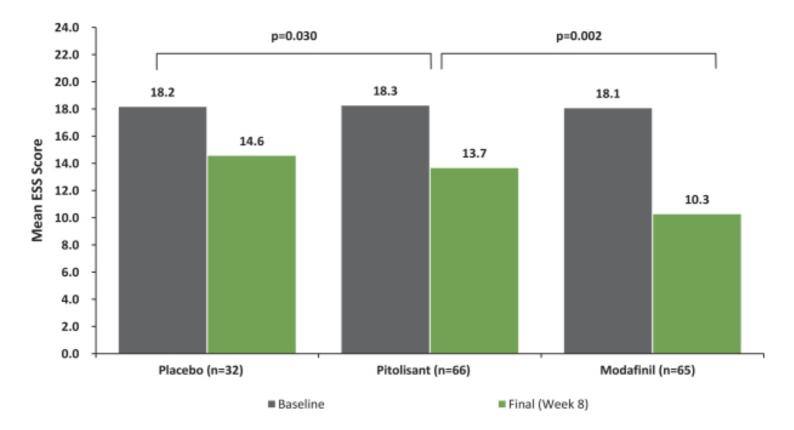
HARMONY 1bis was a randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of pitolisant in adult patients with narcolepsy on improvement in EDS over an eight-week period. This trial was designed in accordance with recommendations from European regulators, and as such, contained both a placebo and active comparator arm. The active comparator was modafinil used in doses up to 400 mg/day. HARMONY 1bis enrolled 165 patients and had flexible dosing during the first three weeks of the trial, followed by five weeks of stable dosing. The maximum dose of pitolisant in this dose-to-effect trial was 17.8 mg and only 76% of the patients were titrated to this dose for the stable dosing period. 75% of the patients had a history of cataplexy.

The primary endpoint in the trial was the ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo. Secondary endpoints included ESS responder rates, MWT, SART, reduction in cataplexy, CGI-C for both EDS and cataplexy, the EQ-5D, and the Patient's Global Opinion on the Effect of Treatment Questionnaire. The main efficacy objective of the trial was to demonstrate superiority of pitolisant compared to placebo on the primary endpoint, while one of the secondary objectives was to explore the non-inferiority of pitolisant compared to modafinil on ESS score.

Efficacy Results

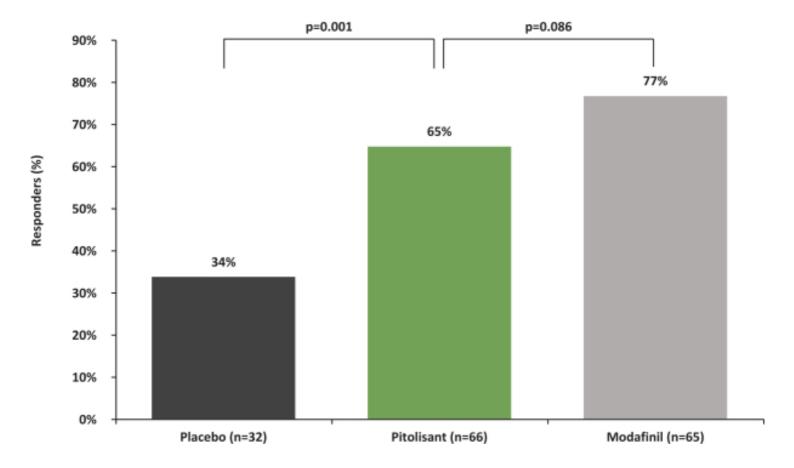
Pitolisant showed a significant reduction in the mean ESS score change from baseline to final visit as compared to placebo (-5.0 versus -2.8, respectively). This resulted in a treatment effect (ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo) of -2.2 (p=0.030). The treatment effect between modafinil and pitolisant was -2.75 and, based on this score and the pre-specified statistical analysis plan, resulted in pitolisant not being non-inferior to modafinil. We believe the same factors that contributed to this result in HARMONY 1 also apply to HARMONY 1bis. In addition, in this trial, the maximum dose of pitolisant to which patients could be titrated (17.8 mg) was not the maximum labeled dose for pitolisant (which is 35.6 mg), and 24% of patients in this trial were on doses lower than 17.8 mg, which means that a substantial percentage of patients were on study drug at an amount less than the maximum approved dose in the USPI for pitolisant. In addition, modafinil was dosed up to 400 mg/day, while the recommended dose of modafinil in its USPI is 200 mg/day, which means that the respective doses of pitolisant and modafinil were not comparable.

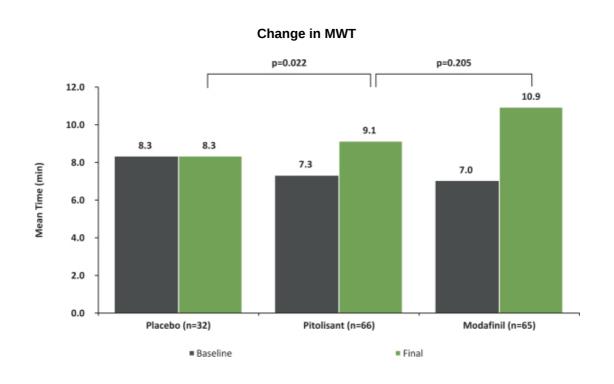
Change in Mean ESS Score



Regarding the secondary endpoints, ESS responder rates (a responder was defined as having a final ESS score £ 10 or change in ESS score 3 3) were significantly greater for those patients treated with pitolisant compared to those on placebo (65% vs. 34%, respectively; p=0.001). The responder rate for patients treated with modafinil was 77% and the difference compared to pitolisant was not statistically significant (p=0.086). On the MWT, pitolisant treatment significantly improved performance when compared to placebo (p=0.022), while improvement was not significantly different compared to modafinil (p=0.294). It should be noted that there was not a prospective plan to control for Type 1 error in this trial.

Responders (Final ESS \pounds 10 or D ESS 3 3)





With regard to other secondary endpoints, the overall pattern of response was that the findings for patients on both pitolisant and modafinil were superior to those on placebo while the responses

were not significantly different for pitolisant and modafinil. The pitolisant group's SART Total Score was significantly improved compared to placebo (p=0.043), while not significantly different compared to modafinil (p=0.407). The CGI-C for EDS showed improvement in 37% of patients on placebo, 72% of patients on pitolisant, and 78% of patients on modafinil. Responses on the CGI-C for cataplexy showed improvement for 60% of patients treated with pitolisant compared to 54% of patients on modafinil and 36% of patients on placebo. However, the difference in the reduction in the daily rate of cataplexy between pitolisant (0.32) and placebo (0.31) was not statistically significant (p=0.873). Lastly, the findings on both the EQ-5D and the Patient's Global Opinion on the Effect of Treatment Questionnaire did not show any meaningful differences between the pitolisant and placebo treatment groups in the HARMONY 1bis trial (no statistical test was performed for the EQ-5D and the p-value for the Patient's Global Opinion on the Effect of Treatment Questionnaire was 0.070).

Safety Results

Pitolisant was generally well tolerated in HARMONY 1bis. Seventy-seven patients experienced a TEAE during the trial: 49% in the pitolisant group, 36% in the placebo group, and 49% in the modafinil group. The most commonly reported TEAEs in the pitolisant treatment group were headache (13%), dizziness (6%), vomiting (4.5%), insomnia (4.5%), and decreased appetite (4.5%). There were no serious adverse events in the pitolisant group and there was one serious adverse event during HARMONY 1bis in the modafinil treatment group, which was not treatment-related. There were no deaths during the trial and no significant changes in laboratory values or hemodynamic parameters (heart rate and blood pressure) from baseline to final visit.

HARMONY CTP

Design

HARMONY CTP was a randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of pitolisant on the reduction in cataplexy in adult patients with narcolepsy with frequent attacks of cataplexy over a seven-week period. HARMONY CTP consisted of 106 patients. The maximum dose of pitolisant in this dose-to-effect trial was 35.6 mg and only 65% of patients reached this dose during the stable dosing period. Both stimulants and wake-promoting agents were prohibited during the trial; only 11% of subjects were on stable doses of anti-cataplectic medications (7% in the pitolisant treatment group and 16% for placebo).

The primary endpoint in HARMONY CTP was the change in the weekly rate of cataplexy, or WRC, from baseline to the stable dosing period (Weeks 4–7). Secondary endpoints included proportion of patients with high cataplexy rate (WRC >15), CGI-C for cataplexy and EDS, mean change in ESS score and percentage of ESS responders, MWT, the EQ-5D, number of days with hallucinations (as recorded in the patient diaries), and Patient's Global Opinion on the Effect of Treatment Questionnaire.

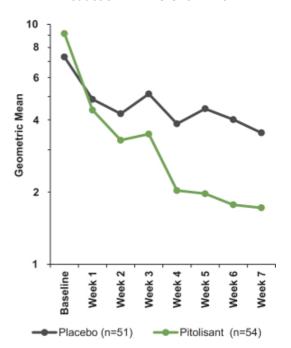
Efficacy Results

In HARMONY CTP, pitolisant resulted in a significantly greater reduction than placebo in the WRC from baseline to the stable dosing period (Weeks 4–7), with a 75% reduction in the pitolisant group compared to 38% on placebo (p<0.0001). Further, significantly fewer patients had WRC >15 at endpoint with pitolisant (6%) versus placebo (24%) (p=0.005). The clinical relevance of these findings was captured by the CGI-C related to cataplexy. Mean CGI-C score was 3.5±1.1 with placebo versus 2.6±1.1 with pitolisant. The mean reduction of the CGI-C score for pitolisant compared with placebo was -0.95 (95% CI (-1.36, -0.54); p<0.0001). Overall positive response rates on the CGI-C related to cataplexy were 33% on placebo and 67% on pitolisant.

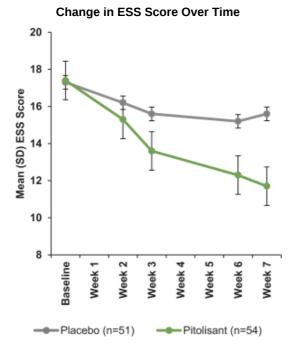
Percent Reduction in WRC

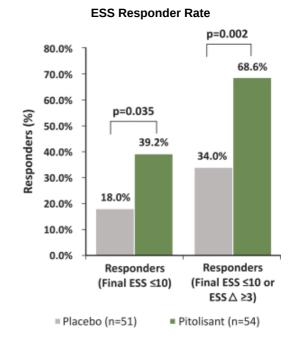
Placebo (n=51) Pitolisant (n=54) 10% 20% 30% 40% 38% 60% 70% 80% P<0.0001

Reduction in WRC Over Time



With regard to other secondary endpoints, pitolisant demonstrated a statistically significant reduction in mean ESS score from baseline to final visit at week seven as compared to placebo (-5.4 vs. -1.9; p=0.0001) and significantly higher ESS responder rates compared to placebo (p=0.035 for Type 1 ESS responders rate and p=0.002 for Type 2 ESS responders rate; see graph below). On the CGI-C related to EDS, the mean score was 3.7 with placebo versus 2.6 with pitolisant, with a mean reduction of -0.99 (p<0.0001). Overall positive response rates on the CGI-C related to EDS were 24% on placebo and 69% on pitolisant. It should be noted that there was not a prospective plan to control for Type 1 error in this trial.





With regard to other secondary endpoints, pitolisant showed a statistically significant improvement on the MWT from baseline to end of trial compared to placebo. Baseline geometric means on the MWT were 4.3 minutes and 3.7 minutes for placebo and pitolisant, respectively, with final MWT values of 4.6 minutes and 7.1 minutes for placebo and pitolisant, respectively; the improvement in MWT was 78% higher with pitolisant compared to placebo (p=0.003). On the Patient's Global Opinion on the Effect of Treatment Questionnaire, overall improvement was reported in 26% of patients on placebo compared to 54% on pitolisant (p=0.001).

Safety Results

Pitolisant was generally well tolerated in HARMONY CTP. Thirty-five patients experienced a TEAE during the trial: 35% in the pitolisant group and 31% in the placebo group. The most commonly reported AE in the pitolisant group in HARMONY CTP was headache, which 9% of the group reported, compared to 10% for the placebo group. Other frequently reported AEs in the pitolisant group were irritability, anxiety and nausea (each reported by 3 patients, or 6%). There were no deaths or serious adverse events during HARMONY CTP and no significant changes in laboratory values or hemodynamic parameters (heart rate and blood pressure) from baseline to final trial visit in either group.

HARMONY 3

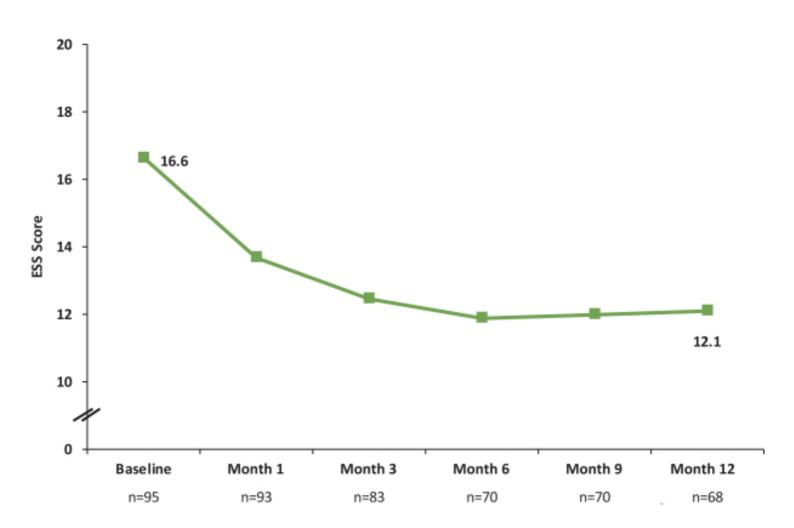
Design

HARMONY 3 was an open-label, real-world trial to assess the long-term safety and tolerability of pitolisant in the treatment of EDS in adult patients with narcolepsy, with or without cataplexy, over a one-year period (with a 5-year extension at the trial sites in France). HARMONY 3 enrolled 104 patients, 102 of whom were treated with pitolisant, and 68 completed out to one year. In HARMONY 3, 75% of patients had a history of cataplexy and 76% of patients who completed out to one year were on the maximum dose of pitolisant of 35.6 mg. For the 5-year extension phase at the trial sites in France, 50 patients were eligible to continue, of which 48 patients elected to do so and 14 of them completed out to 5 years.

Efficacy Results

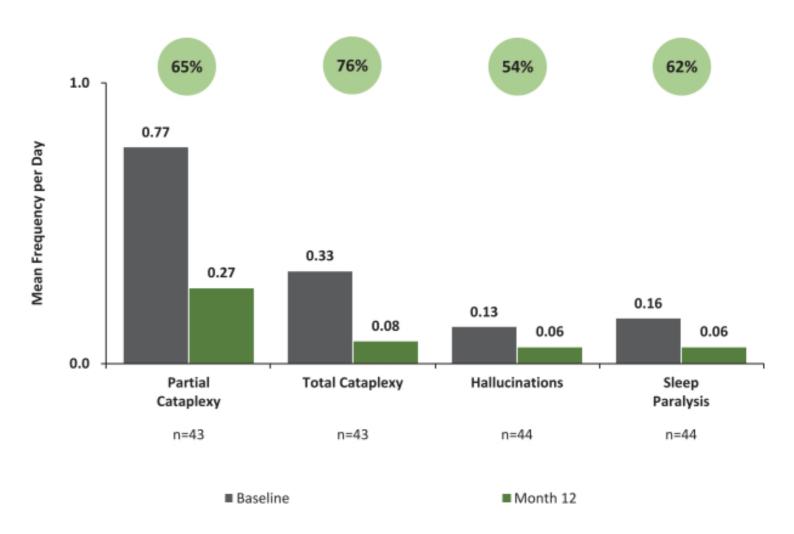
In the 68 patients with data at baseline and at 12 months in HARMONY 3, pitolisant reduced the mean ESS score by -4.63 over this period. The magnitude of the decrease in ESS score was larger in the subgroup of patients (n=86) who were not on pitolisant at trial entry (-5.25) as compared to the subgroup of patients (n=16) who came into the trial on pitolisant from the French Compassionate Use Program (-2.63).

ESS Score Over Time



In HARMONY 3, pitolisant also demonstrated a reduction in cataplexy and other symptoms of REM intrusion into wakefulness from baseline to month 12, showing a reduction of 65% to 76% in partial or total cataplexy attacks, respectively, out to one year. Reductions of more than 50% were also seen for other symptoms of REM dysfunction, such as hallucinations and sleep paralysis.

Reduction in Cataplexy and Other Symptoms of REM Sleep Intrusion into Wakefulness with Pitolisant



Safety Results

Pitolisant was generally well tolerated in HARMONY 3. AEs observed with long-term pitolisant treatment were consistent with those observed in short-term randomized, controlled trials such as HARMONY 1, HARMONY 1bis, and HARMONY CTP. Fifty-eight of the 102 treated patients (57%) reported an aggregate of 168 TEAEs in HARMONY 3, the most common of which are shown in the table below. During the one-year trial, there were no deaths and seven patients reported 10 serious adverse events, nine of which were deemed by the investigator to be unrelated to pitolisant, and one miscarriage which was considered possibly related. No clinically significant changes in laboratory parameters, vital signs or electrocardiogram parameters were recorded over the course of the trial.

Adverse Events (Incidence ³3%), n (%)	Total Population (N=102)
Any adverse event	58 (56.9)
Headache	12 (11.8)
Insomnia	9 (8.8)
Weight increased	8 (7.8)
Anxiety	7 (6.9)
Depression	5 (4.9)
Nausea	5 (4.9)
Irritability	4 (3.9)
Vomiting	4 (3.9)
Vertigo	4 (3.9)

Clinical HAP Trial

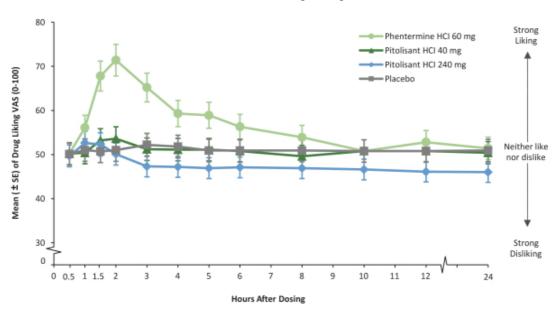
Design

A clinical HAP trial was conducted to evaluate the human abuse potential of pitolisant. In this trial, nondependent, recreational stimulant users able to distinguish phentermine hydrochloride (HCl; 60 mg), a CIV stimulant, from placebo in a drug discrimination test were randomized in a 4-period, double-blind, crossover design to receive single doses of pitolisant 35.6 mg (therapeutic dose), pitolisant 213.6 mg (supra-therapeutic dose), phentermine HCl 60 mg, and placebo. The primary endpoint was maximum effect (Emax) on the 100-point Drug Liking (at the moment) visual analog scale.

Results

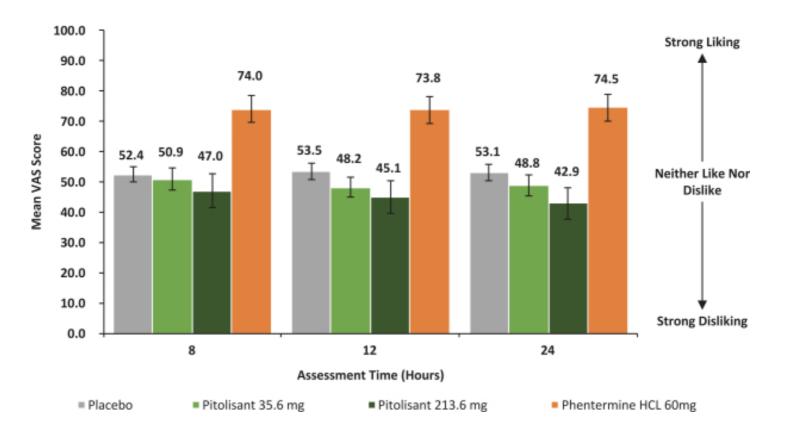
A total of 43 subjects were enrolled and 38 completed the trial. Mean Drug Liking E_{max} was significantly greater for phentermine (78.7) versus pitolisant 35.6 mg (57.3; p<0.0001) and pitolisant 213.6 mg (59.0; p<0.0001). Drug Liking E_{max} was similar for pitolisant (both doses) and placebo (56.1) (p<0.001 for 35.6 mg versus placebo, and p=0.003 for 213.6 mg versus placebo).

Maximum Drug Liking

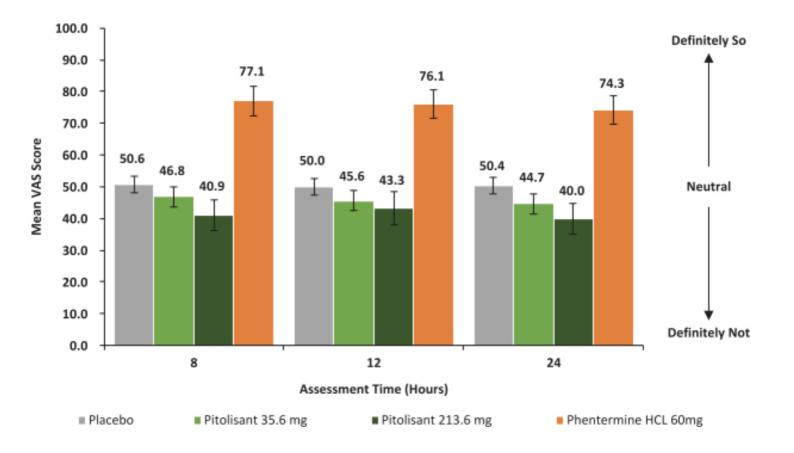


Similarly, for key secondary measures of Overall Drug Liking and willingness to Take Drug Again, mean E_{max} scores were significantly greater for phentermine (77.4 for Overall Drug Liking and 78.7 for Take Drug Again) versus pitolisant 213.6 mg (49.3 and 44.5) and 35.6 mg (52.7 and 49.4) (p < 0.0001 for each comparison for both doses of pitolisant).

Overall Drug Liking



Take Drug Again

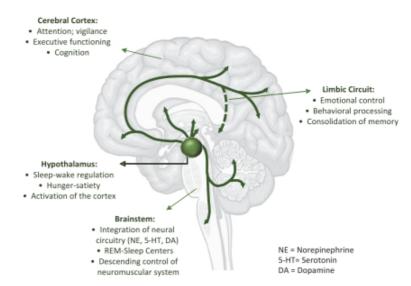


In summary, in the clinical HAP trial, pitolisant demonstrated a statistically significant and clinically relevant reduction in drug liking compared with phentermine as well as an overall response profile similar to placebo. Based on these clinical data, along with data from preclinical abuse liability studies, the evidence pointed to a low risk of abuse for pitolisant, which supported the approval of WAKIX without being scheduled as a controlled substance by the DEA.

Potential New Indications for Pitolisant

We are actively working on label expansion for WAKIX in narcolepsy, including indications for both EDS and cataplexy in pediatric patients. We also intend to work with the FDA toward gaining pediatric exclusivity for WAKIX. In addition, we are evaluating our options regarding the approach to take with the FDA in pursuit of a cataplexy indication in adult patients with narcolepsy, while the FDA is currently re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We believe that pitolisant's ability to regulate histamine and histaminergic signaling gives it the potential to provide therapeutic benefit in other disorders that are mediated through the H3 receptor and histamine signaling. Histamine plays an important role in normal physiologic functioning beyond wakefulness in the areas of attention, vigilance, behavior and cognition. The presence of H3 receptors in the hypothalamus, brainstem and cerebral cortex account for different functions, which could provide an opportunity for pitolisant to treat symptoms other than EDS in different disorders. In addition, H3 receptors are located mainly in the CNS as opposed to other parts of the body outside the CNS. This fact, along with pitolisant being highly selective for the H3 receptor (as opposed to H1 receptors, H2 receptors and H4 receptors), is the reason, we believe, for pitolisant's unique MOA and why it works very differently than anti-histamines (peripheral H1 receptor blockers) or anti-ulcer medications (H2 receptor blockers).

- Role of histamine in normal physiologic functioning beyond wake promotion (e.g. attention, vigilance, behavior, cognition)
- Location of H3 receptors in hypothalamus, brainstem, and cerebral cortex account for different functions (and potential symptoms in different disorders)
- Limited H3 receptor populations outside the CNS



Our initial plan is to seek new indications in patient populations that have symptom overlap with narcolepsy, such as EDS. The initial clinical targets will focus on rare neurological disorders consistent with our overall strategy. We submitted an IND in October 2019 and received acknowledgement from the FDA that the proposed clinical investigation may proceed. We subsequently completed a Phase 1 PK clinical trial in pediatric patients with PWS in the fourth quarter of 2019, and initiated a long-term, open-label safety trial in these patients. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020 and anticipate topline results from this trial in the first half of 2022. We also anticipate commencing a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in adult patients with MD in the first half of 2021 with topline results anticipated in the second half of 2022. While conducting clinical programs to evaluate these indications, other clinical endpoints beyond EDS will be evaluated as secondary or exploratory endpoints, such as behavioral symptoms, vigilance, fatigue and cognition, to broaden the investigation of pitolisant with the hope of generating pilot data to help inform the next phase of our clinical development strategy.

Label Expansion in Narcolepsy

Cataplexy Indication

The NDA submission for WAKIX initially sought approval for the treatment of both EDS and cataplexy in adult patients with narcolepsy. Our application requesting approval for a cataplexy indication was based on our cataplexy results from HARMONY 1 and HARMONY CTP. The FDA approved WAKIX for the treatment of EDS in adult patients with narcolepsy but issued a CRL for the cataplexy indication, and therefore did not approve WAKIX for the treatment of cataplexy in adult patients with narcolepsy. The FDA determined that, although we had submitted one positive clinical trial for cataplexy (HARMONY CTP), the NDA submission did not provide substantial evidence of effectiveness regarding cataplexy. Among other concerns, the FDA did not consider HARMONY 1 as an adequate and well-controlled trial for the cataplexy endpoint. The FDA found that cataplexy was a secondary endpoint in HARMONY 1, and there was no prospective plan to control the Type 1 error rate for secondary endpoints in this trial. The FDA also noted that the subgroup of interest (patients with cataplexy) was defined post hoc, based on event(s) that occurred post-randomization. With regard to HARMONY CTP, the FDA considered it a positive trial, but the FDA commented that its design had certain weaknesses that do not render it the type of trial that could, on its own, provide sufficient evidence of effectiveness to support approval of the cataplexy indication, and the FDA generally requires two adequate and well-controlled clinical studies to support approval. The FDA therefore recommended that we conduct a second trial substantiating the results of HARMONY CTP in order to obtain approval for the cataplexy indication.

A Type A post-CRL meeting was held with the FDA on December 12, 2019 to discuss the cataplexy indication, during which we pointed the FDA to additional analyses that were conducted in support of the HARMONY 1 cataplexy data and which were included in the NDA submission. Following this meeting, the FDA requested further information from us and ran the analyses. Based on these interactions, the FDA informed us that they are re-analyzing some of the data that were submitted in the NDA in support of the adult cataplexy indication. We continue to evaluate our options regarding the approach to take with the FDA in order to obtain an indication for WAKIX for the treatment of cataplexy in adult patients with narcolepsy utilizing the data originally submitted in the NDA.

Pediatric Narcolepsy

Approximately 5% of diagnosed narcolepsy patients (approximately 3,600 patients) are 19 years of age or under. Symptoms often have a more profound effect in children, resulting in reduced function and greater psychological impact. Until the fourth quarter of 2018, no treatments were approved for pediatric narcolepsy, at which time Xyrem received an expanded indication for the treatment of cataplexy and EDS in patients seven years of age or older with narcolepsy. Bioprojet is conducting a Phase 2 clinical trial in pediatric patients with narcolepsy ages six to up to 18 years old with results expected in the second half of 2020. We intend to engage with the FDA in pursuit of pediatric exclusivity and commence a Phase 3 trial in pediatric patients in the second half of 2021 in pursuit of pediatric indications for both EDS and cataplexy. Our current plan is to evaluate approximately 90 to 100 pediatric patients, ages six to up to 18, to assess the safety and efficacy of pitolisant in pediatric narcolepsy patients on improvement in both EDS and reduction in weekly rates of cataplexy.

Develop Pitolisant in New Patient Populations in Pursuit of Additional Indications

Prader-Willi Syndrome

PWS is a rare genetic disorder caused by a loss of function of specific genes on chromosome 15 resulting in hypothalamic dysfunction and decreased levels of hypocretin in some patients with PWS. The hypothalamus controls both sleep-wake states and hunger-satiety; therefore, two of the main

symptoms in patients with PWS are EDS and hyperphagia. Other features include low muscle tone, short stature, behavioral problems and cognitive impairment. It is estimated that approximately one in 15,000 to 20,000 people in the United States suffer from PWS, and over half of those suffering from PWS also have reported or experienced EDS. We submitted an IND in October 2019 and received acknowledgement from the FDA that the proposed clinical investigation may proceed. We subsequently completed a Phase 1 PK clinical trial in pediatric patients with PWS in the fourth quarter of 2019, and initiated a long-term, open-label safety trial in these patients. We intend to commence a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS in the second half of 2020 and anticipate topline results from this trial in the first half of 2022.

PWS poses a heavy burden for both patients and caregivers and there are few therapeutic options available. Current development programs are focused on hyperphagia, with no other programs focusing on EDS or cognitive function. We believe there is a compelling opportunity to impact the EDS component of this disorder as well as other symptoms, such as behavioral issues and cognitive function, for which the mechanism of action of pitolisant could be effective. We have collaborated with the Foundation for Prader-Willi Research, or the FPWR, to advance our clinical program and underscore our commitment to this patient population. We are members of the FPWR Clinical Trials Consortium and are working with members of its Scientific Advisory Board to gain their insights for our development program. Progress to date includes (i) the opening of an IND for PWS on October 28, 2019, (ii) the completion of a Phase 1 PK trial in patients with PWS in the fourth quarter of 2019, with patients actively rolling over into an open-label, long-term safety trial, (iii) the submission of a Phase 2 clinical protocol synopsis to the FDA for their review and comment, and (iv) plans underway to initiate a Phase 2 trial in the second half of 2020.

The proposed Phase 2 clinical trial will be a randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of pitolisant in patients with PWS ages 6 to 65. An estimated 60 to 70 patients will be enrolled at approximately 10 sites across the United States. Patients will be randomized to low-dose pitolisant, high-dose pitolisant or placebo in a 1:1:1 treatment ratio and titrated over three weeks up to their randomized dose, followed by eight weeks of stable dosing. The primary trial objective is to assess for improvement in EDS as measured by the Multiple Sleep Latency Test. Secondary endpoints include several behavioral symptom scales as well as specific measures of cognitive function using validated computer-based assessments. Clinician global impression of disease severity, caregiver global impression of EDS severity, and overall caregiver burden will be measured. Exploratory endpoints include the effect of pitolisant on hyperphagia and measurements of ghrelin levels. Patients who complete the trial will be eligible to participate in an open-label extension phase to assess the long-term safety and effectiveness of pitolisant in patients with PWS, which will run throughout the duration of the PWS development program.

Myotonic Dystrophy

MD is a rare, multi-system genetic disease that affects the neuromuscular system as well as several other systems. It is inherited in an autosomal dominant pattern and there are two main types: type 1, or DM1, and type 2, or DM2. The underlying cause of DM1 is a mutation in the DMPK gene on chromosome 19. DM1 is the most common form of adult-onset muscular dystrophy and affects as many as 140,000 patients in the United States. EDS and fatigue are hallmark clinical characteristics in the majority of patients with DM1 and are referred to as the most frequent non-muscular symptoms in patients with DM1. Cognitive impairment is also a prominent symptom in patients with DM1 and all of these symptoms are thought to be mediated through H3 receptors and histaminergic pathways located throughout the central nervous system, or CNS. DM2 is not as common as DM1 with an estimated prevalence of between 3,000 and 29,000 patients in the United States. The underlying cause of DM2 is a mutation in the CBNP gene on chromosome 3. Patients with DM1 and DM2 share similar phenotypes but disease onset is later in patients with DM2 and symptoms tend to be milder.

The therapeutic application of pitolisant may provide benefits across the key symptoms of EDS and fatigue which are often among the chief complaints of patients with MD. In a survey of 451 DM1 patients, daytime sleepiness and fatigue were second only to muscle weakness in symptom prevalence and impact. Our clinical program will be designed to demonstrate effect on measures of EDS and fatigue, as well as assess performance related to cognitive function, such as attention, vigilance and working memory. Progress to date includes working with key opinion leaders to develop the scientific rationale for the investigation of pitolisant in patients with MD, development of a draft Phase 2 clinical protocol synopsis, and submission of a pre-IND meeting request to the FDA in January 2020. A pre-IND meeting was granted and scheduled for March 16, 2020, to discuss our development plans in patients with DM1, but was cancelled because we deemed the preliminary meeting comments adequate to advance the program forward. We now plan to include both patients with DM1 and patients with DM2 in our trial, and we plan to discuss inclusion of patients with DM2 with FDA. We plan to initiate a Phase 2 clinical trial in the first half of 2021, subject to receiving authorization to proceed from the FDA under an IND we plan to submit.

The proposed Phase 2 clinical trial is a randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of pitolisant in adult patients with MD ages 18 to 65. An estimated 90 to 100 patients will be enrolled at approximately 10 sites across the United States and Europe. Patients will be randomized to low-dose pitolisant, high-dose pitolisant, or placebo in a 1:1:1 treatment ratio and titrated over three weeks up to their randomized dose, followed by eight weeks of stable dosing. The primary trial objective is to assess for improvement in EDS as measured by the MWT and the ESS. Secondary endpoints include assessments of fatigue as well as specific measures of cognitive function using validated computer-based assessments. Clinician and patient global impression of disease severity using the CGI-S and PGI-S, respectively, will be measured as well as patient assessments of overall disease burden. Plasma samples will be collected to generate pharmacokinetic data and a PK/PD analysis will be performed. Patients who complete the trial will be eligible to participate in an open-label extension phase to assess the long-term safety and effectiveness of pitolisant in patients with MD, which will run throughout the duration of the MD development program.

Other Potential Indications

The next phase of clinical development for pitolisant will be guided by the signals generated from the clinical trials described above and other potential trials in PWS and MD. If we observe favorable results in these trials on the symptoms of fatigue and cognitive dysfunction, we plan to investigate pitolisant in other rare neurological patient populations in which these symptoms are a prominent part of the disease process resulting in significant impact on daily functioning.

Manufacturing and Supply

We have secured a commercial drug supply to support the launch of WAKIX in the United States. Although we do not currently own or operate facilities for product manufacturing, storage and distribution, or testing, we have contracted directly with third parties for each of these functions.

Manufacturing is subject to extensive regulation that imposes various procedural and documentation requirements that govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, and more. Our systems and our contractors are required to be in compliance with these regulations, and compliance is assessed regularly through monitoring of performance and a formal audit program.

Our current supply chains for WAKIX involve several manufacturers that specialize in specific operations of the manufacturing process, specifically, intermediate and starting material manufacturing,

drug substance manufacturing, and drug product manufacturing labeling and secondary packaging, and distribution services:

- Interor S.A. manufactures our BF4 and BF6 intermediate and starting material used in the active pharmaceutical ingredient, or API.
- Corden Pharma Chenôve SAS, a full-service contract development and manufacturing organization, or CDMO, manufactures our API.
- Patheon UK Limited, a CDMO owned by Thermo Fisher Scientific Inc., manufactures our finished product tablets and fills them into unlabeled bottles.
- Carton Service, Inc., dba Pharma Packaging Solutions, handles our labeling and secondary packaging.
- Integrated Commercialization Solutions, LLC (ICS), a division of AmerisourceBergen Corporation, is our third-party logistics provider.
- Inmar Rx Solutions, Inc., an advanced technology and data analytics company, specializes in reverse distribution of our product and manages our pharmaceutical returns and product recall, if needed.

Competition

Our industry is highly competitive and subject to rapid and significant change as research provides a deeper understanding of rare neurological disorders, including narcolepsy, and as new therapies are developed. We face potential competition from multiple sources, including large pharmaceutical, biotechnology and specialty pharmaceutical companies. The key competitive factors affecting the success of WAKIX, and any other product candidates that we develop, if approved, are likely to be efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

WAKIX competes with currently FDA-approved products for the treatment of EDS in adult patients with narcolepsy, all of which are controlled substances. Jazz Pharmaceuticals' Xyrem (sodium oxybate) is the only FDA-approved product for the treatment of EDS and cataplexy in adult patients with narcolepsy and, in October 2018, received FDA approval for an expanded indication in patients seven years and older for the treatment of cataplexy and EDS. Xyrem is a Schedule III controlled substance available only through a restricted access REMS program. Provigil and Nuvigil, which are Schedule IV WPAs, and stimulants such as methylphenidate and amphetamine (both Schedule II controlled substances), are approved for the treatment of EDS in narcolepsy. Anti-depressants and certain other agents are sometimes used off-label for the treatment of cataplexy in narcolepsy. Jazz Pharmaceuticals' Sunosi (solriamfetol) was approved by the FDA in March 2019 and launched in July 2019. Sunosi (solriamfetol) is a Schedule IV controlled substance and is indicated to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea. It is not indicated for cataplexy in patients with narcolepsy. Additionally, Jazz Pharmaceuticals is currently working on a lower/low sodium formulation of Xyrem, with an expected approval in the second half of 2020 or beyond, Avadel Pharmaceuticals is working on a once nightly formulation version of sodium oxybate, with approval expected in 2021 or beyond, and Xyrem is expected to go generic in 2023. Beyond 2023, there are other potential future competitive products in development, including Axsome Therapeutics's AXS-12 (reboxetine) product candidate and Takeda's TAK-925/994 (orexin 2 receptor agonist) product candidate.

We believe WAKIX has a safety and efficacy profile that is competitive with each of the products listed above for the treatment of EDS in adult patients with narcolepsy, although WAKIX has not been

compared with these products in head-to-head clinical trials, and that its non-scheduled status represents a distinct competitive advantage relative to those same products. Additionally, WAKIX is priced lower than Xyrem, which we believe is a competitive advantage for WAKIX and may contribute to third-party payor preferences for WAKIX relative to Xyrem. Conversely, WAKIX is priced higher than other competitors such as Provigil, Nuvigil, Sunosi and certain generic competitors, such as methylphenidate and amphetamine, which may contribute to third-party payor preferences for those lower-priced treatment options relative to WAKIX.

Strategic Agreement

License and Commercialization Agreement with Bioprojet

On July 28, 2017, we and Bioprojet entered into a license and commercialization agreement, or the Bioprojet License Agreement. Bioprojet granted to us an exclusive, sublicensable license to commercialize, in the United States and its territories, commonwealths, and protectorates, including Puerto Rico, a product containing pitolisant currently known as WAKIX for narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, Parkinson's disease, and any other indication agreed upon by the parties (which currently include PWS and MD), or the field, as well as rights to related patent rights, know-how, trademarks, trade dress, regulatory filings and approvals, or the Bioprojet Assets. Bioprojet also granted us a co-exclusive (with Bioprojet), sublicensable license to Bioprojet Assets to clinically develop and register the pitolisant product in the field in the United States. Bioprojet retains the right to manufacture the product in the United States, and to develop outside the United States and commercialize other products that contain pitolisant as an active ingredient anywhere in the world. Bioprojet also granted us an exclusive license to use certain trademarks and trade names in connection with the commercialization of the product under the Bioprojet License Agreement.

Under the Bioprojet License Agreement, Bioprojet is responsible for conducting all preclinical studies and clinical trials necessary for achieving and maintaining regulatory approval in the United States for narcolepsy and cataplexy indications, including all costs and expenses. We are responsible for all other costs associated with other development and regulatory activities, unless Bioprojet otherwise agrees to participate in funding such activities. Bioprojet is responsible for filing, with our participation, the initial new drug application for the product with the FDA and is required to transfer such application to us upon approval by the FDA.

Upon approval by the FDA, we were required under the Bioprojet License Agreement to promptly launch the product and use commercially reasonable efforts to commercialize the approved products in the United States in the field for each approved indication. In addition, we are required to deploy a number of sales representatives and spend an amount of expenditure, each as agreed upon in a commercialization plan.

Under the Bioprojet License Agreement, Bioprojet has the right and authority to prepare, file, prosecute and maintain all Bioprojet patents on a worldwide basis at its own cost. Bioprojet shall keep us informed of the course of prosecution and other proceedings in the United States. We have the first right to enforce the licensed patent rights with respect to any infringing products in the United States. If we do not bring an action to enforce such patents against infringing activities that involve such infringing products, Bioprojet has the right to bring such action.

We paid Bioprojet an initial license fee of \$150.0 million, a milestone payment of \$50.0 million upon FDA acceptance of the NDA in February 2019, and a milestone payment of \$75.0 million plus an addition \$2.0 million fee for approval of the NDA in November 2019. We are subject to two further milestone payments: (i) a milestone payment of \$40.0 million upon the attainment of aggregate net sales of WAKIX in the United States of \$500.0 million subsequent to the date of NDA approval by the

FDA and (ii) a milestone payment of \$102.0 million if we receive NDA approval from the FDA for a cataplexy indication, which amount includes a \$2.0 million extension fee. We agreed to pay royalties on the product at tiered royalty rates of 13 to 24% based on annual total net sales during the period commencing on first commercial sale of the product and ending on the latest of 10 years from first commercial sale of the product, expiration of all regulatory exclusivity, or expiration of the last Bioprojet patent covering the product. Such royalty payments are subject to reductions based on royalties paid to any third party in order for us to commercialize the product. We also agreed to pay royalties in consideration for a trademark license at a rate of 3% of net sales for 20 years after first commercial sale of the product. We further agreed to pay minimum royalties during the third through tenth year of the Bioprojet License Agreement if the product is approved for narcolepsy to the extent such minimum royalties exceed the royalties payable as described above, which minimum amounts were calculated based on sales materially below our sales forecast.

The Bioprojet License Agreement will continue until the expiration of the obligation to pay royalties with respect to the product. We and Bioprojet may each terminate the Bioprojet License Agreement for a material breach by the other party that remains uncured for 90 days. Bioprojet may terminate the Bioprojet License Agreement in its entirety if we or our sublicensees challenge the licensed patents. In addition, we and Bioprojet have the right to terminate the Bioprojet License Agreement upon the other party's insolvency.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our WAKIX product and potential future pitolisant-based products, as well as for future product candidates and novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing U.S. and foreign patents and applications relating to our technology, inventions, and improvements that are important to the development and implementation of our business.

Our patent portfolio comprises four U.S. patents exclusively licensed to us from Bioprojet. One U.S. patent, No. 8,207,197, has claims directed to a polymorph, i.e. a specific crystalline form, of pitolisant and, methods for preparing that polymorph of pitolisant, which is expected to expire in February 2029 without taking into consideration any possible patent term extension. Approximately 200 experiments have been performed over the last 20 years and no other stable polymorphs have been isolated. A second U.S. patent, No. 8,486,947, has claims directed to methods of treating excessive daytime sleepiness by administering pitolisant, which is expected to expire in September 2029 without taking into consideration any possible patent term extension. With all applicable patent term adjustments available and granted to us, the term of the last-to-expire pitolisant-related patent in our portfolio extends to September 2029. We may receive additional patent term based on the patent term extension described below.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. The term of a U.S. patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the U.S. Patent and Trademark Office, or the USPTO, during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the

expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug may be extended under the Hatch-Waxman Act. We have applied for patent term extension on two patents covering pitolisant, only one of which will receive patent term extension, if at all. While we have received confirmation from the USPTO that the patents are eligible for patent term extension, there is no guarantee that the applicable authorities, including the USPTO and the FDA, will agree with our assessment of whether such extension should be granted. We estimate the length of such extension to be 389 days; however, the USPTO, in conjunction with the FDA, will calculate the length of such extension and there is no guarantee that their calculation will align with our estimate.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Changes in either the patent laws or their interpretation in the United States may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block potential competitors from practicing the claimed inventions of the issued patents.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

We and/or our licensor also rely on protections under trade secret laws, and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our trade secrets include, for example, certain program specific synthesis, formulations, patient selection strategies and certain aspects of our research. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to us, and as such, will become our property. There can

be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Further, we have in-licensed from Bioprojet the registered trademark product name "WAKIX" in the United States. We also have registered trademark protection in the United States for "KNOW NARCOLEPSY" as well as our brand and logo "HB," "HB HARMONY BIOSCIENCES" and "HARMONY BIOSCIENCES." We also have trademark applications pending with the U.S. Patent and Trademark Office for "REM AT THE WRONG TIME" and "NON-REM AT THE WRONG TIME."

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- · submission to the FDA of an NDA:
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess
 compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and
 controls are adequate to preserve the drug's identity, strength, quality and purity; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing or sale of the drug in the United States; and
- Compliance with any post-approval requirements, including the potential requirement to implement a REMS program or to conduct a post-approval study.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested
 for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its
 effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to
 preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal
 dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in
 well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval,
 to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial

is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision. Specifically, the FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety and quality.

The FDA also may require submission of a REMS to ensure that the benefits of the drug outweigh its risks. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

FDA Expedited Development and Review Programs

The FDA has various programs, including fast track designation, accelerated approval priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast track designation may also be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. The designation includes all of the benefits of a fast track designation. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and

surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls:
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- · fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals:
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing

the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that (i) affects fewer than 200,000 individuals in the United States, or (ii) if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants an orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Among other benefits of an orphan drug designation are tax credits for certain research and a waiver of the user fee for the NDA.

Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated

product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

We received an orphan designation for pitolisant for the treatment of narcolepsy and, upon approval of WAKIX, we received orphan exclusivity until 2026.

DEA Regulation

The Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. The FDA did not recommend that the DEA schedule WAKIX as a controlled substance, and WAKIX is therefore not scheduled as a controlled substance by the DEA.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also regulate controlled substances.

Other Healthcare Laws

In addition to FDA regulation of pharmaceutical products, pharmaceutical companies are subject to federal healthcare laws and regulations as well as regulation by the states and foreign jurisdictions

in which they conduct their business that restrict business practices in the pharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include U.S. federal and state anti-kickback and false claims laws, civil monetary penalties laws, consumer protection and transparency laws as well as similar foreign laws in the jurisdictions outside the U.S., including, without limitation, those laws described below.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery.

The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Federal government price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state antikickback and false claims laws, which may apply to

business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violation of any of such laws or any other governmental regulations that apply may result in significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Data Privacy and Security Laws

Pharmaceutical companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the Department of Health and Human Services, or HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. Furthermore, there can be no assurance that a product will be considered medically reasonable and necessary for a specific indication, that a product will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability to sell a product profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing constitutional challenges in the Fifth Circuit Court and the U.S. Supreme Court, the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended, and we cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through December 31, 2020 under the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Further, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients.

HHS has begun implementation of the Trump administration Blueprint, soliciting feedback on some of these measures and, immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Further, Congress has indicated that it will continue to seek new legislative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. If enacted as written, the Lower Drugs Costs Now Act would require HHS to directly negotiate drug prices with manufacturers. It is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Facilities

Our corporate headquarters are located 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania, where we lease approximately 15,651 square feet of office space. Approximately 40 of our employees are located at our corporate headquarters. We also lease, pursuant to our Right of Use Agreement with Paragon, office space at 330 N. Wabash Ave, Suite 3500, Chicago, Illinois 60611, where eight of our employees are located.

Employees

As of March 31, 2020, we have approximately 150 employees, 101 of whom are dedicated to commercial functions, which includes sales, marketing, market access, commercial operations and insights, and 23 of whom are dedicated to research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. Also, pursuant to our Management Services Agreement with Paragon, at a given time up to six employees of Paragon assist us with regulatory, capital markets and legal transactional matters.

Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

The following table provides information regarding our executive officers and members of our board of directors (ages as of the date of this prospectus):

Name	Age	Position(s)
Executive Officers		
John C. Jacobs	53	Chief Executive Officer, Director
Susan L. Drexler	50	Chief Financial Officer
Jeffrey Dayno, M.D.	62	Chief Medical Officer
Jeffrey Dierks	49	Chief Commercial Officer
Andrew Serafin	46	Chief Business Officer
Non-Employee Directors		
Jeffrey S. Aronin	52	Director, Chairman
Martin Edwards, MBChB	64	Director
Antonio Gracias	49	Director
Jack Bech Nielsen	56	Director
Aaron Royston, M.D.	35	Director
Juan A. Sabater	56	Director
Andreas Wicki, Ph.D.	61	Director

Executive Officers

John C. Jacobs. Mr. Jacobs has served as our Chief Executive Officer and on our board of directors since June 2018. Previously, Mr. Jacobs served as our Executive Vice President and Chief Commercial Officer from October 2017 to June 2018. Prior to joining us, Mr. Jacobs served as the Senior Vice President and General Manager of the Respiratory Business Unit of Teva Pharmaceuticals Industries Ltd., or Teva, a public pharmaceutical company, from September 2017 to October 2017. He also served as Senior Vice President of Commercial Operations and Innovation of Teva, from September 2016 to September 2017, and as Vice President and General Manager of Teva's Branded Business in Canada from July 2014 to September 2016. Mr. Jacobs has held positions of increasing scope and responsibility at major pharmaceutical companies including Cephalon Inc., a former public biopharmaceutical and biotechnology company, Wyeth, LLC, a public pharmaceutical company, and Pfizer Inc., a public pharmaceutical and biotechnology company. He has over 25 years of commercial, operations, business and leadership experience across multiple therapeutic areas including central nervous system, sleep disorders, pain care and respiratory, as well as rare disease and other specialty markets.

Mr. Jacobs received a B.S. in business from State University of New York College at Plattsburgh and an M.B.A. from The State University of New York at Binghamton. We believe that Mr. Jacobs is qualified to serve on our board of directors due to his skills and experience in brand marketing in the biopharmaceutical industry.

Susan L. Drexler. Susan L. Drexler has served as our Chief Financial Officer since October 2019. From April 2018 to June 2019, Ms. Drexler served in various roles as the Interim Chief Financial Officer and Vice President of Business Development at Ocugen, Inc. From August 2015 to November 2017, Ms. Drexler served in senior roles in Business Development and Market Intelligence roles at AmerisourceBergen Corporation. From July 2007 to June 2015, Ms. Drexler held a senior development finance role at Shire Pharmaceuticals. Earlier in her career, Ms. Drexler held roles of increasing responsibility in finance consulting at Duff & Phelps, LLC and senior audit roles at PricewaterhouseCoopers LLP. Ms. Drexler earned a B.S. in Accounting from Albright College and an M.B.A. from the Joseph M. Katz Graduate School of Business at the University of Pittsburgh. Ms. Drexler is a Certified Public Accountant in the State of Pennsylvania.

Jeffrey Dayno, M.D. Dr. Dayno has served as our Chief Medical Officer since November 2017. Dr. Dayno also served as Chief Medical Officer of Eaglet Co., now known as Zyla Life Sciences, from July 2014 to October 2017. Prior to joining Eaglet Co., Dr. Dayno served as Vice President of Global Medical Affairs at ViroPharma, Inc., from August 2011 to January 2014, at which time it was acquired by Shire Pharmaceuticals. Since March 2016, Dr. Dayno has served on the board of directors of Atrin Pharmaceuticals, LLC, a private biopharmaceutical company. Dr. Dayno completed his residency in neurology at Temple University Hospital then completed a fellowship in stroke and cerebrovascular diseases at Henry Ford Hospital in Detroit, Michigan, as part of a National Institutes of Health program grant in stroke. He has over 10 years of experience in clinical and academic medicine and was on the faculty at Jefferson Medical College. Dr. Dayno also has over 20 years of experience in the pharmaceutical industry in leadership roles in companies including Merck & Co., Inc., a public pharmaceutical company, and Cephalon Inc., a formerly public biopharmaceutical and biotechnology company, which was acquired by Teva. He was one of the founding members and served as the Chairman of the Board of the Philadelphia Stroke Council, a non-profit organization dedicated to patient awareness and professional education to advance the efforts toward acute stroke treatment. Since March 2013, Dr. Dayno has been a member of the board of visitors of Temple University School of Medicine. Dr. Dayno received a B.A. in international studies from Trinity College and an M.D. from Temple University School of Medicine.

Jeffrey Dierks. Mr. Dierks has served as our Chief Commercial Officer since July 2018. Prior to his role as Chief Commercial Officer, Mr. Dierks served as our Vice President of Marketing from October 2017 to July 2018. Prior to joining Harmony, Mr. Dierks served in senior marketing roles leading the U.S. Pain Care & Wakefulness portfolio from June 2014 to December 2016 and U.S. Migraine Marketing from December 2016 to October 2017 at Teva Pharmaceuticals. Before joining Teva, Mr. Dierks held commercial roles of increasing responsibility at several major pharmaceutical companies, including Janssen Pharmaceuticals Inc., Endo Pharmaceuticals and Wyeth Pharmaceuticals. In 2017, PM360 magazine honored Mr. Dierks as a transformational leader in the pharmaceutical industry and in 2010 with the Trailblazer Award. Mr. Dierks has over 20 years of commercial experience and has led brand teams across numerous therapeutic areas including central nervous system, sleep disorders, pain care and migraines, as well as rare diseases. Mr. Dierks received a B.A. in political science from Western Maryland College and an M.B.A. in marketing from Temple University's Fox School of Business.

Andrew Serafin. Mr. Serafin has served as our Chief Business Officer since December 2018. Mr. Serafin previously served as our Senior Vice President of Business Development and Corporate Strategy from September 2017 to December 2018. Previously, Mr. Serafin served as the Vice President of Business Development at Marathon Pharmaceuticals, LLC, a private development-stage biopharmaceutical company, from August 2015 to May 2017. He also served as the Vice President of Business Development and General Counsel of AltaThera Pharmaceuticals, LLC, a private pharmaceutical company, from April 2015 to August 2015, and the Vice President of Deal Integration and Associate General Counsel of Lundbeck Inc., or Lundbeck, from July 2006 to March 2015. He also served as acting General Counsel of Lundbeck for six months during his time with the company. Mr. Serafin has over 20 years of experience in mergers and acquisitions and corporate legal counseling in the pharmaceutical, healthcare and technology sectors. He received a B.S. in finance from University of Illinois at Urbana-Champaign, a J.D. from Loyola University Chicago School of Law and an M.B.A. from Northwestern University Kellogg School of Management.

Directors

John C. Jacobs. Mr. Jacobs' business background information is set forth under "Executive Officers" above.

Jeffrey S. Aronin. Mr. Aronin founded Harmony Biosciences and has served on our board of directors and as non-executive Chairman since October 2017. In June 2017, Mr. Aronin founded

Paragon Biosciences which he leads as Chairman and Chief Executive Officer. Paragon Biosciences is a life science innovator that invests in, builds, and advises a portfolio of bioscience companies. In addition to serving on our board, Mr. Aronin serves on the boards of other Paragon privately-held portfolio companies, including Qlarity Imaging, LLC, which develops artificial intelligence-enabled diagnostic tools, Castle Creek Pharma, LLC, which is dedicated to rare genetic dermatology, Emalex Biosciences Inc., which is dedicated to treating neurological conditions, and Skyline Biosciences, LLC, which is dedicated to treating oncology conditions. From January 2011 to May 2017, Mr. Aronin was the Chairman and Chief Executive Officer of Marathon Pharmaceuticals, LLC, a private research-based biopharmaceutical company that developed drugs for rare diseases, which was subsequently acquired by PTC Therapeutics. Prior to that, Mr. Aronin founded Ovation Pharmaceuticals, Inc., or Ovation, where he served as President and Chief Executive Officer from 2000 to 2009. After Lundbeck A/S acquired Ovation in 2009, Mr. Aronin served as Chief Executive Officer of Lundbeck Inc. until 2011. Since June 2008, Mr. Aronin has served on the public board of directors of Discover Financial Services, Inc. Mr. Aronin also currently serves on the boards of several non-profit organizations including The Aspen Institute and MATTER, which Aronin founded to support life science innovation. Mr. Aronin received a B.S. in marketing from Northern Illinois University and an M.B.A. from DePaul University. We believe that Mr. Aronin is qualified to serve on our board of directors due to his vast skills and experience in biopharmaceutical strategy, innovation, business development, commercialization, lifecycle management, capital structure and finance.

Martin Edwards, MBChB. Dr. Edwards has served on our board of directors since August 2017. He has served in various roles and most recently as a Senior Partner at Novo Holdings A/S, a Danish private limited liability company, since October 2003. In this capacity, Dr. Edwards also serves on the boards of Nuvelution Pharma, Inc., Inozyme Pharma, Inc., Karus Ltd., F2G Ltd., and Vantia Therapeutics Ltd. He is also independent chairman of the board of directors of KalVista Pharmaceuticals, Inc. and an independent board member of Verona Pharma PLC, both public biopharmaceutical companies. Previously, Dr. Edwards served on the board of directors of CoLucid Pharmaceuticals, Inc., also a public biopharmaceutical company, from September 2015 to January 2017 and on the board of directors of private biotechnology companies. Dr. Edwards holds an MBChB from the University of Manchester and an M.B.A. from the University of Warwick. He is a member of the Royal College of Physicians, a member with distinction of the Royal College of General Practitioners and a Fellow of the Faculty of Pharmaceutical Medicine.

Antonio J. Gracias. Mr. Gracias has served on our board of directors since September 2017. Since September 2001, Mr. Gracias has been Chief Executive Officer and Chief Investment Officer of Valor Management LLC, or Valor, a private equity firm. Mr. Gracias has served as a director of Castle Creek Pharmaceuticals since September 2018. He also served as a director of Marathon Pharmaceuticals, LLC from November 2013 until its acquisition by PTC Therapeutics in May 2017, and SolarCity Corporation from 2012 to 2016. Mr. Gracias has served on the board of directors of Tesla, Inc., since May 2007, including as Lead Independent Director from September 2010 to April 2019. Mr. Gracias also serves as director of SpaceX. He has over 20 years of experience investing in a variety of sectors including private equity, public equity and real estate transactions. Mr. Gracias received a joint B.S. / M.S.F.S. degree in international finance and economics from Georgetown University School of Foreign Service and a J.D. from the University of Chicago Law School. We believe that Mr. Gracias is qualified to serve on our board of directors due to his skills and experience in investment strategy, portfolio company management and improvement, and finance in several industries, including pharmaceuticals and healthcare.

Jack B. Nielsen. Mr. Nielsen has served on our board of directors since September 2017. Mr. Nielsen has served as a Managing Director at Vivo Capital, LLC, a healthcare-focused investment firm, since August 2017, and as a consultant at Vivo Capital from March 2017 to July 2017. From April 2001 to February 2017, Mr. Nielsen worked within the Novo Holdings A/S venture activities in several

roles, most recently being employed as a Senior Partner. Mr. Nielsen has served on the board of directors of Reata Pharmaceuticals, Inc., a public pharmaceutical company, since June 2006. He has also served on the board of directors of Aligos Therapeutics, Inc. since August 2018 and MacuLogix, Inc. since March 2019. Mr. Nielsen previously served on the board of directors of public biotechnology companies including Crinetics Pharmaceuticals, Inc, Merus, N.V., Apollo Endosurgery, Inc. and Akebia Therapeutics, Inc. He also served on the board of directors of several private biotechnology and pharmaceutical companies including PROCEPT BioRobotics Co., Kanyos Bio, Inc., Unchained Labs, Inc., Anokion Therapeutics, Alios Biopharma, Inc. and ProteinSimple, Inc. Mr. Nielsen received a M.Sc. in chemical engineering from the Technical University of Denmark and a Masters in management of technology and economics from the Center for Technology, Economics and Management at the Technical University of Denmark. We believe that Mr. Nielsen is qualified to serve on our board of directors due to his experience as a venture capitalist and serving on various biotechnology and biopharmaceutical company boards.

Aaron Royston, M.D. Dr. Royston has served as a member of our board of directors since September 2017. Dr. Royston is a Partner at venBio Partners, a life sciences investment firm, and has been with venBio Partners since November 2015. Prior to joining venBio Partners, Dr. Royston worked for Vivo Capital, a global life sciences investment firm from July 2014 to November 2015. Previously, he worked at Bain & Company from July 2013 to July 2014, where he advised biotechnology companies on a broad range of strategic and operational issues. Earlier in his career, Dr. Royston coordinated clinical research at Mount Sinai Medical Center, where his research has been published and presented in multiple medical journals and conferences. In 2011, Dr. Royston was recognized by the Obama Administration as a Champion of Change for his work in technology and innovation. Dr. Royston serves on the board of directors of Akero Therapeutics, a public biotechnology company, and previously served on the board of Menlo Therapeutics, Inc., a public biotechnology company, and currently serves on the board of directors of several private companies. Dr. Royston received a B.S. in biological sciences from Duke University, and an M.D. and M.B.A. from the University of Pennsylvania. We believe that Dr. Royston is qualified to serve on our board of directors due to his clinical and biotechnology industry experience.

Juan A. Sabater. Mr. Sabater has served on our board of directors since 2017. Mr. Sabater has served in various roles at Valor since 2010, most recently as President. Prior to joining Valor, Mr. Sabater was a Managing Director of Goldman Sachs & Co. in their Investment Banking Division, from 1998 to 2006. He also currently serves on the board of several private companies and organizations including The Frick Collection and Girls Who Code Inc. Mr. Sabater currently serves as the Co-Chairman of Augeo Affinity Marketing, Inc., and also sits on the board of trustees of The Hewitt School. He received an A.B. in history from Princeton University and a J.D. from Stanford Law School. Mr. Sabater was also a former officer in the U.S. Army Reserve. We believe that Mr. Sabater is qualified to serve on our board of directors due to his expansive skillset including his management experience with a nationally recognized private equity firm and an investment banking company, along with his demonstrated business acumen.

Andreas Wicki, Ph.D. Dr. Wicki has served on our board of directors since September 2017. Dr. Wicki has served as Chief Executive Officer of HBM Healthcare Investments AG (formerly HBM BioVentures AG) since July 2001. From 1998 to 2001, Dr. Wicki was the Senior Vice President of the European Analytical Operations at MDS Inc. From 1990 to 1998, he was co-owner and Chief Executive Officer of ANAWA Laboratorien AG and Clinserve AG, two life sciences contract research companies. Dr. Wicki currently serves on the board of directors of Pacira BioSciences, Inc., a public pharmaceutical company, Buchler GmbH, HBM Healthcare Investments (Cayman) Ltd., HBM BioCapital Ltd., Viela Bio, Inc., a public clinical-stage biotechnology company, and Vitaeris, Inc., a private clinical-stage biopharmaceutical company. Dr. Wicki is a life sciences entrepreneur and investor with over 20 years of experience in the pharmaceutical and biotechnology industries. Dr. Wicki

holds an M.Sc. and Ph.D. in chemistry from the University of Bern, Switzerland. We believe Dr. Wicki is qualified to serve on our board of directors due to his extensive experience with pharmaceutical companies, his financial expertise and his years of experience providing strategic and advisory services to pharmaceutical and biotechnology organizations.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of our Board of Directors

Our board of directors currently consists of eight directors. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that our board of directors may consist of up to directors and that our board of directors will be divided into three classes, as nearly equal in number as possible, with the directors in each class serving for a three-year term, and one class being elected each year by our stockholders. Dr. Edwards will resign as one of our directors immediately prior to the effectiveness of the registration statement on Form S-1, of which this prospectus forms a part.

When considering whether directors have the experience, qualifications, attributes or skills, taken as a whole, to enable our board of directors to satisfy its oversight responsibilities effectively in light of our business and structure, the board of directors focuses primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

Director Independence

Prior to the consummation of this offering, our board of directors undertook a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that Messrs.

and are each an "independent director," as defined under the Exchange Act and the rules of Nasdaq.

Committees of Our Board of Directors

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and standing committees. We will have a standing audit committee, nominating and corporate governance committee and compensation committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Audit Committee

Our audit committee will be responsible for, among other things:

- · appointing, compensating, retaining, evaluating, terminating and overseeing our independent registered public accounting firm;
- · discussing with our independent registered public accounting firm their independence from management;

- · reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting
 firm the interim and annual financial statements that we file with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls and compliance with legal and regulatory requirements;
- reviewing our policies on risk assessment and risk management;
- · reviewing related party transactions; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal
 controls or auditing matters.

Upon the consummation of this offering, our audit committee will consist of Messrs. and Mr. serving as chair. Rule 10A-3 of the Exchange Act and the rules require that our audit committee have at least one independent member upon the listing of our common stock, have a majority of independent members within 90 days of the date of this prospectus and be composed entirely of independent members within one year of the date of this prospectus. Our board of directors has each meet the definition of "independent director" for purposes affirmatively determined that Messrs. and of serving on the audit committee under Rule 10A-3 and the Nasdaq rules. Each member of our audit committee meets the financial literacy requirements of Nasdag listing standards. In addition, our board of directors has determined that Mr. "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors will adopt a new written charter for the audit committee, which will be available on our principal corporate website at www.harmonybiosciences.com substantially concurrently with the consummation of this offering. The information on or accessed through our website is deemed not to be incorporated in this prospectus or to be part of this prospectus.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will be responsible for, among other things:

- identifying individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors;
- · evaluating the overall effectiveness of our board of directors and its committees; and
- reviewing developments in corporate governance compliance and developing and recommending to our board of directors a set
 of corporate governance guidelines and principles.

Upon the consummation of this offering, our nominating and corporate governance committee will consist of Messrs. , and , with Mr. serving as chair. Our board of directors will adopt a new written charter for the nominating and corporate governance committee, which will be available on our principal corporate website at www.harmonybiosciences.com substantially concurrently with the consummation of this offering. The information on or accessed through our website is deemed not to be incorporated in this prospectus or to be part of this prospectus.

Compensation Committee

Our compensation committee will be responsible for, among other things:

- · reviewing and approving the compensation of our directors, Chief Executive Officer and other executive officers; and
- · appointing and overseeing any compensation consultants.

Upon the consummation of this offering, our compensation committee will consist of Messrs. , and , with Mr. serving as chair. Our board has determined that Messrs. , and are "non-employee directors" as defined in Section 16b-3 of the Exchange Act. Our board of directors will adopt a new written charter for the compensation committee, which will be available on our principal corporate website at www.harmonybiosciences.com substantially concurrently with the consummation of this offering. The information on or accessed through our website is deemed not to be incorporated in this prospectus or to be part of this prospectus.

Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed under "Risk Factors" in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Risk Considerations in our Compensation Program

We conducted an assessment of our compensation policies and practices for our employees and concluded that these policies and practices are not reasonably likely to have a material adverse effect on our Company.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee (or other committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Ethics and Code of Conduct

Prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code will be posted on our website, www.harmonybiosciences.com. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code. The information on or accessed through our website is deemed not to be incorporated in this prospectus or to be part of this prospectus.

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2019 Summary Compensation Table" below. In 2019, our "named executive officers" and their positions were as follows:

- · John C. Jacobs, Chief Executive Officer;
- · Jeffrey Dayno, Chief Medical Officer;
- · Andrew Serafin, Chief Business Officer; and
- · John Vittoria, former Chief Financial Officer.

Mr. Vittoria served as our Chief Financial Officer from November 2018 until October 2019, and transitioned out of the Company in November 2019.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

2019 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2019.

Name and Principal Position John C. Jacobs Chief Executive Officer	Salary (\$) 454,000	Bonus (\$)(1) 391,575	Option Awards _(\$)(2) 	All Other Compensation (\$)(3)	Total (\$) 845,663
Jeffrey Dayno Chief Medical Officer	414,000	238,050	20,000	148	672,175
Andrew Serafin Chief Business Officer	340,500	195,788	_	754	537,042
John Vittoria former Chief Financial Officer	281,875	_	_	451,420	733,295

⁽¹⁾ Amounts reported include actual annual bonuses earned in 2019 under our annual bonus program to reward each of the named individuals' contributions to the Company in 2019. We provide additional information regarding the annual bonuses in "—Narrative to Summary Compensation Table—2019 Bonuses" below.

⁽²⁾ Amounts reflect the full grant-date fair value of stock options granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all option awards made to executive officers in Note 3 to our financial statements included elsewhere in this prospectus.

⁽³⁾ Amounts reported include Company-paid perquisites, gross-up payments to cover personal income taxes pertaining to Company-paid long-term disability coverage (\$45, \$106, \$37 and \$71 for Messrs. Jacob, Dayno, Serafin and Vittoria, respectively) and, with respect to Mr. Vittoria, severance benefits (\$451,313).

Narrative to Summary Compensation Table

2019 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our Company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

The annual base salaries for Messrs. Jacobs, Dayno, Serafin and Vittoria for 2019 were \$454,000, \$414,000, \$340,500 and \$307,500, respectively. Effective January 1, 2020, the base salaries payable to Messrs. Jacobs, Dayno and Serafin increased by 4.2% to \$473,068, \$431,388 and \$354,801, respectively.

2019 Bonuses

Under our annual bonus program, our board of directors may approve, in its discretion, annual cash bonuses based on its assessment of the applicable executive's performance for the year. In 2019, each of Messrs. Jacobs, Dayno and Serafin was eligible to earn a discretionary cash bonus targeted at \$340,500, \$207,000 and \$170,250, respectively, to reward their contributions to the Company. In connection with Mr. Serafin's promotion to Chief Business Officer, the Company increased Mr. Serafin's target bonus opportunity from 40% to 50% of his base salary, effective January 1, 2019. For calendar year 2019, the actual annual cash bonuses earned by each of Messrs. Jacobs, Dayno and Serafin were \$391,575, \$238,050 and \$195,788, respectively.

Each of these cash bonuses awarded to or earned by the named executive officers in 2019 are set forth above in the Summary Compensation Table in the column entitled "Bonus."

Equity Compensation

Certain of our named executive officers currently hold stock option awards under the Harmony Biosciences II, Inc. Equity Incentive Plan, or the Equity Incentive Plan. Specifically, in 2019, Mr. Dayno was granted stock options covering a number of shares of our common stock as set forth below. The options generally vest in equal installments on the first five anniversaries of the applicable vesting commencement date, subject to continued employment through the applicable vesting date, and accelerate in full upon a "change in control" (as defined in the Equity Incentive Plan). For additional information about the Equity Incentive Plan, please see the section titled "—Executive Compensation Plans—Equity Incentive Plan" below.

The following table sets forth the stock option awards granted to our named executive officers in the 2019 fiscal year.

Named Executive Officer
Jeffery Dayno

Number of Shares Subject to Options Granted in 2019

50,000

We intend to adopt a 2020 Incentive Award Plan, referred to below as the 2020 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our Company and certain of its affiliates and to enable our Company and certain of its affiliates to obtain and retain services of these individuals, which is essential to our long-term success. We expect that the 2020 Plan will be effective on the date on which it is adopted by our board of directors, subject to approval of such plan by our stockholders. For additional information about the 2020 Plan, please see the section titled "—Executive Compensation Plans—2020 Incentive Award Plan" below.

Other Elements of Compensation

Retirement Plans

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Internal Revenue Code, or the Code, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. We did not make any matching contributions in 2019 under our 401(k) plan.

Employee Benefits and Perquisites

Health/Welfare Plans. All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- · medical, dental and vision benefits;
- · medical and dependent care flexible spending accounts; and
- · short-term and long-term disability insurance.

We also provide life insurance and accidental death and dismemberment insurance to our vice presidents and above, including our named executive officers, that is over and above the insurance provided to our full-time employees generally.

We believe the perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

Tax Gross-Ups

We make gross-up payments to cover the personal income taxes of our full-time employees, including our named executive officers that pertain to the Company-paid long-term disability coverage provided by us.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2019.

		Option Awards				
Grant Date	Vesting Commencement Date (1)	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Op	tion Exercise Price (\$)	Option Expiration Date
10/2/2017	10/1/2017	1,034,273	1,551,410	\$	1.00	10/2/2027
10/1/2018	10/1/2018	200,000	800,000	\$	1.00	10/1/2028
11/13/2017	11/1/2017	340,000	510,000	\$	1.00	11/13/2028
1/7/2019	1/1/2019	_	50,000	\$	1.00	1/7/2029
10/1/2017	10/1/2017	400,000	600,000	\$	1.00	10/1/2027
10/1/2018	10/1/2018	30,000	120,000	\$	1.00	10/1/2028
11/14/2018	11/1/2018	80,000	_	\$	1.00	2/28/2020
	10/2/2017 10/1/2018 11/13/2017 1/7/2019 10/1/2017 10/1/2018	Grant Date Commencement Date (1) 10/2/2017 10/1/2017 10/1/2018 10/1/2018 11/13/2017 11/1/2017 1/7/2019 1/1/2019 10/1/2017 10/1/2017 10/1/2018 10/1/2018	Grant Date Vesting Commencement Date (1) Securities Underlying Underlying Unexercised Options (#) Exercisable 10/2/2017 10/1/2017 1,034,273 10/1/2018 10/1/2018 200,000 11/13/2017 11/1/2017 340,000 1/7/2019 1/1/2019 — 10/1/2017 10/1/2017 400,000 10/1/2018 10/1/2018 30,000	Number of Securities Underlying Unexercised Options (#) Unexercisable Underlying Unexercised Options (#) Unexercisable Underlying Unexercised Options (#) Unexercisable Underlying Unexercisable Underlying Unexercised Options (#) Unexercisable Underlying Unexercised Options (#) Unexercisable Underlying Unexercised Options (#) Unexercisable Underlying	Number of Securities Underlying Unexercised Options (#) Unexercisable Unex	Number of Securities Underlying Unexercised Options (#) Exercisable Unexercisable Unexercisable Unexercisable Unexercisable Unexercisable Unexercisable Unexercisable Unexercisable Price (\$) 10/2/2017

(1) 20% of the shares of our common stock underlying the stock options vest and become exercisable annually on the first five anniversaries of the vesting commencement date, subject to continued employment through the applicable vesting date, and accelerate in full upon the occurrence of a "change in control" (as defined in the Equity Incentive Plan).

Executive Compensation Arrangements

The following summarizes the material terms of the employment offer letters and employment agreements with each of our named executive officers.

John C. Jacobs Employment Agreement

On September 6, 2017, we entered into an employment agreement with John C. Jacobs. Under the agreement, Mr. Jacobs' employment will continue until terminated upon written notice by either party in accordance with the employment agreement.

Pursuant to his employment agreement, Mr. Jacobs is entitled to receive an annual base salary of \$400,000 per year; as noted above, Mr. Jacobs' 2019 annual base salary was \$454,000. In addition, Mr. Jacobs (and his spouse and/or eligible dependents) are eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees with comparable responsibilities.

Mr. Jacobs is eligible to earn annual discretionary cash bonuses, determined by our board of directors (or a subcommittee thereof) in its sole discretion based on its assessment of individual and our performance. Mr. Jacobs' target bonus and maximum bonus opportunities are 50% and 75%, respectively, of his annual base salary. The payment of any annual bonus, to the extent any annual bonus becomes payable, will be contingent upon Mr. Jacob's continued employment through the applicable payment date.

In connection with entering into his employment agreement, Mr. Jacobs was awarded a stock option to purchase 2,585,683 shares of our common stock. The option vests as to 20% of the shares underlying the option on each of the first five anniversaries of the grant date, subject to Mr. Jacobs continued employment with the Company through each applicable vesting date, provided, that upon a "change in control" (as defined in Mr. Jacobs' employment agreement), Mr. Jacobs' stock option will accelerate and vest in full subject to his continued employment through such date.

Under his employment agreement, if Mr. Jacobs' employment is terminated without "cause" or due to his resignation for "good reason" (each, as defined in his employment agreement), then, subject to his timely execution and non-revocation of a general release of claims, he will be eligible to receive (i) 12 months of continued payment of base salary; (ii) 12 months of continued coverage under our group health plans at the same level and cost to Mr. Jacobs as was in place prior to the termination date; and (iii) up to three months of outplacement services. If either such termination occurs within 12 months following a "change in control," then, in addition to the payments and benefits described above, Mr. Jacobs will receive a lump-sum cash payment equal to his target annual bonus for the year in which the termination occurs, pro-rated through the date of such termination.

Mr. Jacobs' employment agreement contains customary confidentiality provisions, as well as standard non-compete and employee non-solicitation restrictions effective during employment and for one year thereafter. Mr. Jacobs' employment agreement includes a "best pay" provision under Section 280G of the Code, pursuant to which any "parachute payments" that become payable to him will be reduced so that such payments are not subject to the excise tax under Section 4999 of the Code.

Jeffrey Dayno Offer Letter

On October 10, 2017, we entered into an offer letter with Jeffrey Dayno. Mr. Dayno's employment under the offer letter is at-will, and will continue until terminated at any time by either party.

Pursuant to his offer letter, Mr. Dayno is entitled to receive an annual base salary of \$400,000 per year; as noted above, Mr. Dayno's 2019 annual base salary was \$414,000. In addition, Mr. Dayno is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Mr. Dayno is eligible to earn annual cash bonuses under our bonus program, based on the achievement of individual performance goals relating to our growth and overall performance. Mr. Dayno's target bonus opportunity is 50% of his annual base salary. The payment of any annual bonus, to the extent any such bonus becomes payable, will be contingent upon Mr. Dayno's continued employment through the applicable payment date.

In connection with entering into his offer letter, Mr. Dayno was awarded a stock option to purchase 850,000 shares of our common stock. The option vests as to 20% of the shares underlying the option on each of the first five anniversaries of Mr. Dayno's employment start date, subject to his continued employment with the Company through each applicable vesting date, provided, that upon a "change in control" (as defined in the Equity Incentive Plan), Mr. Dayno's stock option will accelerate and vest in full subject to his continued employment through such date.

Andrew Serafin Offer Letter

On September 8, 2017, we entered into an offer letter with Andrew Serafin. Mr. Serafin's employment under the offer letter is at-will, and will continue until terminated at any time by either party.

Pursuant to this offer letter, Mr. Serafin is entitled to receive an annual base salary of \$300,000 per year; as noted above, Mr. Serafin's 2019 annual base salary was \$340,500. In addition, Mr. Serafin is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Mr. Serafin is eligible to earn annual cash bonuses under our bonus program, based on the achievement of individual performance goals relating to our growth and overall performance. Pursuant to his offer letter, Mr. Serafin's target bonus opportunity is up to 40% of his annual base salary, and, as noted above, Mr. Serafin's 2019 target bonus opportunity was increased to 50% of his annual base salary. The payment of any annual bonus, to the extent any such bonus becomes payable, will be contingent upon Mr. Serafin's continued employment through the applicable payment date.

In connection with entering into his offer letter, Mr. Serafin was awarded a stock option to purchase 1,000,000 shares of our common stock. The option vests as to 20% of the shares underlying the option on each of the first five anniversaries of the grant date, subject to Mr. Serafin's continued employment with the Company through each applicable vesting date, provided, that upon a "change in control" (as defined in the Equity Incentive Plan), Mr. Serafin's stock option will accelerate and vest in full subject to his continued employment through such date.

John Vittoria Offer Letter; Separation Arrangement

On September 29, 2018, we entered into an offer letter with John Vittoria. Mr. Vittoria left the Company on November 30, 2019.

Pursuant to this offer letter, Mr. Vittoria was entitled to receive an annual base salary of \$300,000 per year; as noted above, Mr. Vittoria's 2019 annual base salary was \$307,500. In addition, Mr. Vittoria was eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Mr. Vittoria was eligible to earn annual cash bonuses under our bonus program, based on the achievement of individual performance goals relating to our growth and overall performance. Mr. Vittoria's target bonus opportunity was 40% of his annual base salary.

In addition, under his offer letter, Mr. Vittoria was eligible to receive a relocation allowance of \$45,000 in connection with his relocation from New York to Philadelphia to begin his employment with us. This relocation allowance was paid in a lump sum to Mr. Vittoria in calendar year 2018; provided that Mr. Vittoria did not voluntarily terminate his employment with us on or prior to the first anniversary of his start date, or November 12, 2019. Mr. Vittoria was not required to pay back the relocation allowance to the Company in connection with his separation.

In connection with his offer letter, Mr. Vittoria was awarded a stock option to purchase 400,000 shares of our common stock. As of Mr. Vittoria's termination date, 80,000 shares subject to his option were vested and unexercised and these vested shares will remain outstanding and exercisable until February 28, 2020. The remaining shares underlying Mr. Vittoria's stock option were cancelled and forfeited.

In addition, in connection with Mr. Vittoria's departure from the Company, as noted above, Mr. Vittoria received the following severance benefits: (i) an aggregate amount equal to his annual base salary, payable in a lump sum; (ii) 12 months of continued coverage under our group health plans at the same level and cost to Mr. Vittoria as was in place prior to the termination date; and (iii) a pro-rated 2019 bonus.

Director Compensation

In 2019, we did not provide compensation to our non-employee directors.

However, in connection with this offering, we intend to approve and implement a compensation program for our non-employee directors that consists of annual retainer fees and long-term equity awards. The program is expected to provide directors with a subject to continued service on our board of directors. Each is expected to be denominated as a . In addition, each non-employee director is expected to receive an annual cash retainer for his or her services in an amount equal to \$ and an annual equity award in a denominated dollar value equal to \$

Executive Compensation Plans

The following summarizes the material terms of the long-term incentive compensation plan in which our NEOs will be eligible to participate following the consummation of this offering and the Equity Incentive Plan under which we have previously made periodic grants of equity and equity-based awards to our NEOs and other key employees.

Equity Incentive Plan

Our board of directors and our stockholders approved the Equity Incentive Plan on August 7, 2017.

Under the Equity Incentive Plan, 35,496,000 shares of our common stock are reserved for issuance under the plan. The maximum amount of shares that may be granted with respect to stock option awards and/or stock appreciation rights, or SARs, under the Equity Incentive Plan is 13,333,000 and no more than 3,549,600 shares may be granted to any one participant with respect to incentive stock options, or ISOs. The Equity Incentive Plan will expire in December 2027 unless earlier terminated by our board of directors. Following the effectiveness of the 2020 Plan, the Equity Incentive Plan will terminate and we will not make any further awards under the Equity Incentive Plan. However, any outstanding awards granted under the Equity Incentive Plan will remain outstanding, subject to the terms of the Equity Incentive Plan and applicable award agreement. Shares of our common stock subject to awards granted under the Equity Incentive Plan that expire, lapse or are terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited following the effective date of the 2020 Plan will become available for issuance under the 2020 Plan in accordance with its terms.

Administration. The board of directors (or the compensation committee) administers the Equity Incentive Plan. Subject to the provisions of the Equity Incentive Plan, the administrator has the authority to designate the persons to whom awards are to be made; determine the types of awards to grant; determine the number of shares to be subject to such awards; determine the terms and conditions of any award; grant fully-vested awards; determine whether, and under what circumstances, awards may be settled or exercised in cash, shares, awards or other property; interpret, administer or reconcile any consistency or defect in the Equity Incentive Plan or in any award agreement; establish, amend, suspend or waive any rules and regulations and appoint such agents as the administrator shall deem appropriate to administer the Equity Incentive Plan; accelerate the vesting or exercisability of awards; and make any other determination and take any other action that the administrator deems necessary or desirable for the administration of the Equity Incentive Plan.

Eligibility. Awards under the Equity Incentive Plan may be granted to individuals who are our current or prospective employees, consultants and members of our board of directors.

Awards. The Equity Incentive Plan permits the award of stock options, including ISOs and nonqualified stock options, or NSOs, SARs, restricted stock, restricted stock units, or RSUs, and stock bonuses. To date, only stock options and restricted stock have been granted under the Equity Incentive Plan and only awards of stock options remain outstanding.

- Stock Options and SARs. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- Restricted Stock. Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions. Participants granted restricted stock under the Equity Incentive Plan may, to the extent applicable, have the right to vote such stock and to receive dividends with respect to such stock.
- RSUs. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain
 forfeitable unless and until specified conditions are met and may

be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the Equity Incentive Plan.

- Stock Bonus Awards. Stock bonus awards are awards of fully vested shares of our common stock and awards
 denominated in the shares of our common stock, each of which may be granted to participants and may also be available
 as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to
 which a participant is otherwise entitled.
- Dividends and Dividend Equivalents. Dividends and dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards of RSUs or restricted stock. Dividends and dividend equivalents are credited as of the dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

Corporate Transactions. In the event of a "change in control" (as defined in the Equity Incentive Plan), all outstanding awards will be subject to the terms of the applicable award agreement or, if such treatment is not specified in the applicable award agreement, the applicable merger, purchase or reorganization agreement. All of the award agreements underlying the outstanding option awards provide for full acceleration on a change in control. In addition, in the event of a corporate transaction or change in capital structure, the board of directors may provide for the equitable adjustment of the terms of outstanding awards, the substitution, assumption or termination of all outstanding awards, or cancellation of all outstanding awards in exchange for a cash payment in an amount equal to the fair market value of the shares of our common stock subject to the awards immediately prior to the consummation of such transaction (less any exercise price, as applicable). Prior to any such adjustment, the Company will give notice of such adjustment to the participants holding outstanding awards.

Amendment or Termination of the Equity Incentive Plan and Awards Thereunder. Our board of directors may terminate, amend or modify the Equity Incentive Plan at any time, subject to the written consent of any participant whose rights under the plan would be materially and adversely affected as a result of such termination, amendment or modification. However, to the extent necessary to comply with any applicable law or stock exchange rule, stockholder approval of any amendment or modification to an award must be obtained to reduce the option price per share after the option has been granted or to substitute any outstanding option or SAR award. As described above, the Equity Incentive Plan will terminate as of the effective date of the 2020 Plan.

2020 Incentive Award Plan

We intend to adopt the 2020 Incentive Award Plan, or the 2020 Plan, subject to approval by our stockholders, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2020 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2020 Plan and, accordingly, this summary is subject to change.

Eligibility and Administration. Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries, will be eligible to receive awards under the 2020 Plan.

Following our initial public offering, the 2020 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our board of directors and/or officers (referred to, collectively, as the plan administrator below), subject to certain limitations that may be imposed under the 2020 Plan, Section 16 of the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2020 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2020 Plan, including any vesting and vesting acceleration conditions.

Shares Available. An aggregate of shares of our common stock will be available for issuance under awards granted pursuant to the 2020 Plan, which shares may be authorized but unissued shares, or shares purchased in the open market.

Notwithstanding anything to the contrary in the 2020 Plan, no more than shares of our common stock may be issued pursuant to the exercise of ISOs under the 2020 Plan.

The number of shares available for issuance will be increased by (i) the number of shares of common stock that remain available for issuance under the Equity Incentive Plan as of the effective date of the 2020 Plan, (ii) the number of shares represented by awards outstanding under our Equity Incentive Plan that expire, lapse or are terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited following the effective date of the 2020 Plan, with the maximum number of shares to be added to the 2020 Plan pursuant to clauses (i) and (ii) above equal to shares, and (iii) an annual increase on the first day of each calendar year beginning January 1, 2021 and ending on and including January 1, 2030, equal to the lessor of (A) of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors.

If an award under the 2020 Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2020 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2020 Plan or the Equity Incentive Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2020 Plan or the Equity Incentive Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2020 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2020 Plan will not reduce the shares available for grant under the 2020 Plan. However, the following shares may not be used again for grant under the 2020 Plan: (i) shares subject to SARs that are not issued in connection with the stock settlement of the SAR on exercise, and (ii) shares purchased on the open market with the cash proceeds from the exercise of options.

Awards granted under the 2020 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2020 Plan but will count against the maximum number of shares that may be issued upon the exercise of ISOs.

The 2020 Plan provides that the sum of any cash compensation and the aggregate grant date fair value (determined as of the date of the grant under ASC Topic 718, or any successor thereto) of all awards granted to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed the amount equal to \$750,000, increased to \$1,000,000, in the fiscal year of a non-employee director's initial service as a non-employee director.

Awards. The 2020 Plan provides for the grant of stock options, including ISOs and NSOs, SARs, restricted stock, dividend equivalents, RSUs and other stock or cash based awards. Certain awards under the 2020 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2020 Plan will be evidenced by award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- Stock Options and SARs. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- Restricted Stock. Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions.
- RSUs. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2020 Plan.
- Other Stock or Cash Based Awards. Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled.
- Dividend Equivalents. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of the dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

Certain Transactions. The plan administrator has broad discretion to take action under the 2020 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2020 Plan and outstanding awards. In the

event of a change in control of our Company (as defined in the 2020 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards will become fully vested and exercisable in connection with the transaction. Awards under the 2020 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant.

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments. The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw-back policy implemented by our Company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With regard to tax withholding, exercise price and purchase price obligations arising in connection with awards under the 2020 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable.

Plan Amendment and Termination. Our board of directors may amend or terminate the 2020 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2020 Plan, may materially and adversely affect an award outstanding under the 2020 Plan without the consent of the affected participant, and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws or to increase the director limit. The plan administrator will have the authority, without the approval of our stockholders, to "reprice" any stock option or SAR, or cancel any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. The 2020 Plan will remain in effect until the tenth anniversary of the date the board of directors adopted the 2020 Plan, unless earlier terminated by our board of directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following are summaries of certain provisions of transactions within the past three years to which we have been a party, in which the amount involved exceeds or will exceed \$120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or immediate family member thereof, had or will have a direct or indirect material interest, and are qualified in their entirety by reference to all of the provisions of such agreements.

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm's-length transactions.

Related Party Agreements in Effect Prior to this Offering

Series A Convertible Preferred Stock

From September 22, 2017 through January 8, 2018, we issued and sold an aggregate of 285,000,000 shares of our Series A convertible preferred stock, or Series A stock, at a purchase price of \$1.00 per share for aggregate consideration of approximately \$285.0 million.

The participants in this convertible preferred stock financing included certain holders of more than 5% of our capital stock and their affiliates. The following table sets forth the aggregate number of shares of Series A stock issued to these related parties in this convertible preferred stock financing:

	Shares of	Total	
<u>Stockholder</u>	Series A Stock	Purchase Price	
Valor IV Pharma Holdings, LLC	75,000,000	\$ 75,000,000	
Entities affiliated with FMR LLC (Fidelity)(1)	40,000,000	\$ 40,000,000	
HBM Healthcare Investments (Cayman) Ltd.	30,000,000	\$ 30,000,000	
Entities affiliated with Vivo Capital LLC(2)	30,000,000	\$ 30,000,000	
Marshman Fund Trust II	25,000,000	\$ 25,000,000	
Novo Holdings A/S	25,000,000	\$ 25,000,000	
VenBio Global Strategic Fund, II, L.P.	25,000,000	\$ 25,000,000	
Quantum Strategic Partners Ltd.	11,400,000	\$ 11,400,000	

⁽¹⁾ Consists of 10,934,380 shares of Series A convertible preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, 6,514,984 shares of Series A convertible preferred stock purchased by Fidelity Growth Company Commingled Pool: Fidelity Management & Trust Co., 2,550,636 shares of Series A convertible preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, 3,606,378 shares of Series A convertible preferred stock purchased by Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund, 1,195,827 shares of Series A convertible preferred stock purchased by Variable Insurance Products Fund IV: Health Care Portfolio, 10,935,215 shares of Series A convertible preferred stock purchased by Fidelity Select Portfolios: Health Care Portfolio, and 4,262,580 shares of Series A convertible preferred stock purchased by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund.

Series B Convertible Preferred Stock

On January 8, 2018, we issued and sold an aggregate of 8,000,000 shares of our Series B convertible preferred stock, or Series B stock, at a purchase price of \$1.25 per share for aggregate consideration of approximately \$10.0 million.

⁽²⁾ Consists of 26,360,000 shares of Series A convertible preferred stock purchased by Vivo Capital Fund VIII, L.P. and 3,640,000 shares of Series A convertible preferred stock purchased by Vivo Capital Surplus Fund VIII, L.P.

The participants in this convertible preferred stock financing included certain holders of more than 5% of our capital stock and their affiliates. The following table sets forth the aggregate number of shares of Series B stock issued to these related parties in this convertible preferred stock financing:

	Shares of	Total
<u>Stockholder</u>	Series B Stock	Purchase Price
Quantum Strategic Partners Ltd.	6,080,000	\$ 7,600,000

Series C Convertible Preferred Stock

On August 9, 2019, we issued and sold an aggregate of 25,510,205 shares of our Series C convertible preferred stock, or Series C stock, at a purchase price of \$1.96 per share for aggregate consideration of approximately \$50.0 million.

The participants in this convertible preferred stock financing included certain holders of more than 5% of our capital stock and their affiliates. The following table sets forth the aggregate number of shares of Series C stock issued to these related parties in this convertible preferred stock financing:

	Shares of		Total
<u>Stockholder</u>	Series C Stock	Series C Stock Pu	
Entities affiliated with FMR LLC (Fidelity)(1)	11,948,907	\$	23,419,858
HBM Healthcare Investments (Cayman) Ltd.	3,241,219	\$	6,352,789
Novo Holdings A/S	1,860,107	\$	3,645,810
Valor IV Pharma Holdings, LLC	1,786,985	\$	3,502,491
Entities affiliated with Vivo Capital LLC(2)	1,714,286	\$	3,360,001
Entities affiliated with Quantum Strategic Partners Ltd.(3)	1,712,544	\$	3,356,586

- (1) Consists of 664,710 shares of Series C convertible preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, 2,404,058 shares of Series C convertible preferred stock purchased by Fidelity Growth Company Commingled Pool, 2,033,272 shares of Series C convertible preferred stock purchased by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, 2,067,257 shares of Series C convertible preferred stock purchased by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund, 1,845,926 shares of Series C convertible preferred stock purchased by Fidelity Select Portfolios: Health Care Portfolio, 427,082 shares of Series C convertible preferred stock purchased by Variable Insurance Products Fund IV: Health Care Portfolio, 1,486,194 shares of Series C convertible preferred stock purchased by Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund, and 1,020,408 shares of Series C convertible preferred stock purchased by Fidelity Select Portfolios: Pharmaceutical Portfolio.
- (2) Consists of 1,506,286 shares of Series C convertible preferred stock purchased by Vivo Capital Fund VIII, L.P. and 208,000 shares of Series C convertible preferred stock purchased by Vivo Capital Surplus Fund VIII, L.P.
- (3) Consists of 1,709,116 shares of Series C convertible preferred stock purchased by QSIP LP and 3,428 shares of Series C convertible preferred stock purchased by SCI Partners LP.

Management and Other Agreements

We are party to a management services agreement, or the Management Services Agreement, with Paragon Biosciences, LLC, or Paragon, entered into on September 22, 2017, or the Effective Date, pursuant to which Paragon provides to us certain professional services. In addition, the Chairman of our Board of Directors, Jeffrey S. Aronin, is the Chairman and Chief Executive Officer of Paragon. Marshman Fund Trust I holds 99% of the LLC interests of Paragon. Mr. Aronin serves as the sole trustee of Marshman Fund Trust I and has sole voting and dispositive power with respect to such

LLC interests. In exchange for services provided to us under the Management Services Agreement, we pay to Paragon a management fee of \$0.3 million per each calendar month. This fee is reduced to \$0.2 million per each calendar month following the third anniversary of the Effective Date. For each of the years ended December 31, 2019 and 2018, we incurred approximately \$4.0 million in management fee expense and other expenses to Paragon, which are included in general and administrative expense in the consolidated financial statements of operations. We have the right to terminate the Management Services Agreement upon the consummation of this offering. However, in the event such termination occurs prior to the fourth anniversary of the Effective Date, the terms of the Management Services Agreement require us to pay to Paragon 100% of the remaining amounts to be paid to Paragon under the Management Services Agreement between the date of such termination and the fourth anniversary of the Effective Date. We currently plan to terminate the Management Services Agreement upon the consummation of this offering.

We are also party to a right of use agreement with Paragon whereby we have access to and the right to use certain office space leased by Paragon in Chicago, Illinois. For the year ended December 31, 2019, we incurred fee of \$0.4 million pursuant to this agreement and this amount was paid during the three months ended March 31, 2020.

On March 30, 2018, we entered into an agreement regarding an office lease at 1033 Skokie Boulevard whereby we paid to an affiliate of Paragon \$0.4 million to offset the costs of an early termination of the lease by such affiliate and we entered into a new office space lease with the landlord. The lease expired January 31, 2020.

Second Amended and Restated Investors' Rights Agreement

In connection with the issuance of our Series C preferred stock on August 9, 2019, we entered into a Second Amended and Restated Investors' Rights Agreement, or the IRA, pursuant to which certain holders of our preferred stock, or the Preferred Investors, many of which are beneficial holders of more than 5% of our capital stock or are entities with which certain of our directors are affiliated, are (and following the closing of this offering will be) entitled to rights with respect to the registration of their shares under the Securities Act, as described in additional detail below. Consistent with the Preferred Investors' obligations under the IRA, in connection with this offering, each Preferred Investor that has registration rights agreed not to sell or otherwise dispose of any securities without the prior written consent of the underwriters for a period of 180 days after the date of this prospectus, subject to certain terms and conditions. For more information regarding such restrictions, see the section captioned "Underwriting."

Demand Registration Rights

Pursuant to the IRA, the Preferred Investors are entitled to certain demand registration rights, including to demand registration of their registrable securities 180 days following the completion of this offering. The Preferred Investors holding more than 50% of the registrable securities have the right to require us, on not more than five occasions, to file a registration statement under the Securities Act in order to register the resale of their shares of common stock. We may, in certain circumstances, defer such registrations, and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

Piggyback Registration Rights

If we propose to register the offer and sale of any of our securities under the Securities Act, in connection with the public offering of such securities, the Preferred Investors will be entitled to certain "piggyback" registration rights, allowing them to request to include their registrable securities in such registration, subject to certain limitations. If our proposed registration involves an underwriting, the

managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

S-3 Registration Rights

After we are qualified for registration on Form S-3, the Preferred Investors, as holders of registrable securities, may make a written request that we register the offer and sale of their shares on Form S-3, *provided* that no such registration is required to be made (i) during the period that is 30 days before the Company's good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration or (ii) at such time as we have effected two such registrations in the last 12 months. We may, in certain circumstances, defer such registrations, and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

Expenses

Subject to specified conditions and limitations, we are required to pay all expenses, other than underwriting discounts and commissions, stock transfer taxes, and fees and disbursements of counsel for any holder (except selling holder counsel) incurred in connection with any exercise of these registration rights.

Indemnification

The IRA contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling holders of registrable securities in the event of any damages from an untrue (or allegedly untrue) statement of a material fact or an omission (or alleged omission) of a material fact in the applicable registration statement attributable to us or our violation of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law, and the selling stockholders are obligated to indemnify us for any damages from an untrue (or allegedly untrue) statement of a material fact or an omission (or alleged omission) of a material fact in the applicable registration statement attributable to us or our violation of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law, only to the extent that such damages arise out of or are based upon actions or omissions made in reliance upon the written information furnished by or on behalf of such selling stockholder(s), subject to certain limitations.

Termination

The registration rights terminate upon the earliest of: (i) such date after the completion of this offering on which all shares of registrable securities may be sold during any three (3) month period pursuant to Rule 144 of the Securities Act, (ii) the fifth anniversary of the completion of this offering, (iii) the occurrence of a deemed liquidation event or (iv) the date that no registrable securities remain outstanding that have not previously been sold to the public pursuant to a registration or in reliance on Rule 144 of the Securities Act.

Second Amended and Restated Voting Agreement

In connection with the issuance of our Series C preferred stock on August 9, 2019, we entered into a Second Amended and Restated Voting Agreement, or the Voting Agreement, which, among other things, provides the terms for the voting of shares with respect to the constituency of our board of directors. Pursuant to the terms of the Voting Agreement, the following directors were elected to serve

as members of our board of directors, and, as of the date of this prospectus, continue to so serve: Jeffrey S. Aronin, John C. Jacobs, Antonio Gracias, Juan A. Sabater, Jack Bech Nielsen, Martin Edwards, Aaron Royston and Dr. Andreas Wicki. Mr. Aronin was selected to serve on our board of directors as designated by Marshman Fund Trust II, Mr. Jacobs was selected to serve on our board of directors as our CEO, Messrs. Gracias and Sabater were selected to serve on our board of directors as designated by Valor IV Pharma Holdings, LLC, or the Valor Directors, Mr. Nielsen was selected to serve on our board of directors as designated by Vivo Capital Fund VIII, L.P., and Vivo Capital Surplus Fund VIII, L.P., or the Vivo Director, Mr. Edwards was selected to serve on our board of directors as designated by Novo Holdings A/S, or the Novo Director, Mr. Royston was selected to serve on our board of directors as designated by venBio Global Strategic Fund II, L.P., or the venBio Director, Dr. Wicki was selected to serve on our board of directors as designated by HBM Healthcare Investments (Cayman) Ltd., together with the Valor Directors, the Vivo Director, the Novo Director and the venBio Director and the Series A Directors, possess relevant industry experience and are acceptable to a majority of the Preferred Investors as parties to the Voting Agreement.

The Voting Agreement, including its provisions concerning the rights of certain of the Preferred Investors to designate directors, will terminate automatically upon the consummation of this offering.

Second Amended and Restated Right of First Refusal and Co-Sale Agreement

In connection with the issuance of our Series C preferred stock on August 9, 2019, we entered into a Second Amended and Restated Right of First Refusal and Co-Sale Agreement, or the ROFR and Co-Sale Agreement, with certain of our Preferred Stockholders, many of which are beneficial holders of more than 5% of our capital stock or are entities with which certain of our directors are affiliated. The ROFR and Co-Sale Agreement, among other things: (a) grants our investors certain rights of first refusal and co-sale with respect to proposed transfers of our securities by certain Preferred Stockholders; and (b) grants us certain rights of first refusal with respect to proposed transfers of our securities by certain Preferred Stockholders.

The ROFR and Co-Sale Agreement will automatically terminate immediately prior to the completion of this offering.

Employment Agreements

We intend to enter into an employment agreement with each of our named executive officers in connection with this offering. See "Executive Compensation—Executive Compensation Arrangements."

Director and Officer Indemnification and Insurance

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. We have also purchased directors' and officers' liability insurance. See "Description of Capital Stock—Limitations on Liability and Indemnification of Officers and Directors."

Our Policy Regarding Related Party Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interests, improper valuation or the perception thereof. Prior to the consummation of this offering, our board of directors will adopt a written policy on transactions with related persons that is in conformity with the requirements for issuers having publicly held common stock that is listed on the Nasdag . Under the new policy:

• any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by a committee of the board of

directors composed solely of independent directors who are disinterested or by the disinterested members of the board of directors; and

any employment relationship or transaction involving an executive officer and any related compensation must be approved by
the compensation committee of the board of directors or recommended by the compensation committee to the board of directors
for its approval.

In connection with the review and approval or ratification of a related person transaction:

- management must disclose to the committee or disinterested directors, as applicable, the name of the related person and the
 basis on which the person is a related person, the material terms of the related person transaction, including the approximate
 dollar value of the amount involved in the transaction, and all the material facts as to the related person's direct or indirect
 interest in, or relationship to, the related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction
 complies with the terms of our agreements governing our material outstanding indebtedness that limit or restrict our ability to
 enter into a related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction
 will be required to be disclosed in our applicable filings under the Securities Act or the Exchange Act, and related rules, and, to
 the extent required to be disclosed, management must ensure that the related person transaction is disclosed in accordance with
 the Securities Act and the Exchange Act and related rules; and
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction constitutes a "personal loan" for purposes of Section 402 of the Sarbanes-Oxley Act.

In addition, the related person transaction policy provides that the committee or disinterested directors, as applicable, in connection with any approval or ratification of a related person transaction involving a non-employee director should consider whether such transaction would compromise the director's status as an "independent" or "non-employee" director, as applicable, under the rules and regulations of the SEC, Nasdaq and the Code.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of reflecting the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock, in each case immediately prior to the closing of this offering, and (iii) as adjusted to give effect to this offering, for:

- · each person known by us to beneficially own more than 5% of our common stock;
- · each of our directors;
- · each of our named executive officers; and
- · all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder as described in this prospectus is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, or other rights, held by such person that are currently exercisable or will become exercisable within 60 days of the date of this prospectus, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The percentage ownership of each individual or entity after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of shares of our common stock, in each case immediately prior to the closing of this offering, and before this offering is computed on the basis of total shares of our common stock outstanding, in each case, immediately following the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, in each case immediately prior to the closing of this offering (other than this offering). Unless otherwise indicated, the address of all listed stockholders is 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania 19462.

Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Shai	es beneficially offeri	owned prior to thing	e	Shares beneficially owned after the offering			
Name of beneficial owner	Common stock	Options exercisable within 60 days	Aggregate number of shares beneficially owned	%	Assuming no exercise of option to purchase additional shares	%	Assuming exercise of option to purchase additional shares	%
5% or more stockholders:								
Valor IV Pharma Holdings, LLC(1)								
Entities affiliated with FMR LLC (Fidelity) (2)								
HBM Healthcare Investments (Cayman) Ltd.(3)								
Entities affiliated with Vivo Capital LLC(4)								
Marshman Fund Trust II(5)								
Novo Holdings A/S(6)								
Entities affiliated with Quantum Strategic Partners Ltd.(7)								
venBio Global Strategic Fund II LP(8)								
Named executive officers and directors:								
John C. Jacobs								
Jeffrey Dayno								
Andrew Serafin								
John Vittoria								
Jeffrey S. Aronin								
Martin Edwards(6)								
Antonio Gracias(1)								
Jack Bech Nielsen(4)								
Aaron Royston(8)								
Juan A. Sabater(1)								
Andreas Wicki(3)								
All current directors and executive officers as a group (11 persons)								

* Represents beneficial ownership of less than 1% of outstanding shares of our common stock.

Antonio Gracias, who is one of our directors, is the Chief Executive Officer of Valor Management L.P. and Juan Sabater, who is one of our directors, is President of Valor Management L.P. Valor Management L.P. is the managing member of Valor Equity Capital IV LLC, which is the general partner of Valor Equity Associates IV L.P., which, in turn, is the general partner of each of Valor Equity Partners IV L.P., Valor Equity Partners IV-B L.P., or the Valor Funds. The Valor Funds are the sole members of Valor IV Pharma Holdings, LLC. As such, Antonio Gracias and Juan Sabater may be deemed to have beneficial ownership of the shares held by Valor IV Pharma Holdings, LLC, which consist of (i) shares of common stock and (ii) shares of common stock issuable upon the deemed conversion of preferred stock held by Valor IV Pharma Holdings, LLC. Each of Antonio Gracias and Juan Sabater disclaim beneficial ownership over the shares described above except to the extent of their

- pecuniary interests therein. The address of Valor IV Pharma Holdings, LLC, Antonio Gracias and Juan Sabater is c/o Valor Equity Partners, 875 North Michigan Avenue, Suite 3214, Chicago, IL 60611.
- (2)Consists of (i) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (ii) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Growth Company Commingled Pool, (iii) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund, (v) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Variable Insurance Products Fund IV: Health Care Portfolio, shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Select Portfolios: Health Care Portfolio, (vii) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund, and (viii) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Fidelity Select Portfolios: Pharmaceuticals Portfolio. The address for each of the entities affiliated with FMR LLC and identified above is 245 Summer Street, Boston, Massachusetts 02210.
- (3) Consists of shares of common stock issuable upon the deemed conversion of shares of preferred stock held by HBM Healthcare Investments (Cayman) Ltd. Andreas Wicki, who is one of our directors, indirectly controls HBM Healthcare Investments (Cayman) Ltd. Andreas Wicki disclaims beneficial ownership over the shares described above except to the extent of his pecuniary interests therein, if any. The address for Andreas Wicki is Bundesplatz 1, CH-6301 Zug, Switzerland. The address for HBM Healthcare Investments (Cayman) Ltd. is Governor's Square, Suite 4-212-2, 23 Lime Tree Bay Ave., P.O. Box 30852, Grand Cayman, KY1-1204, Cayman Islands.
- (4) Consists of (i) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Vivo Capital Fund VIII, L.P. and (ii) shares of common stock issuable upon the deemed conversion of shares of preferred stock held by Vivo Capital Surplus Fund VIII, L.P. Jack Nielsen, who is one of our directors, is a Managing Director of Vivo Capital LLC, the management company of Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The address for Jack Nielsen and each of the entities affiliated with Vivo Capital LLC and listed above is c/o Vivo Capital LLC, 192 Lytton Avenue, Palo Alto, CA 94301.
- (5) Consists of (i) shares of common stock and (ii) shares of common stock issuable upon the deemed conversion of preferred stock held by Marshman Fund Trust II, or the Marshman Shares. Charles Harris, Lisa Aronin and Greg Aronin, serve as the trustees of Marshman Fund Trust II and as a result each may be deemed to beneficially own the Marshman Shares. Each of the trustees disclaims any such beneficial ownership of the Marshman Shares. The address for Marshman Fund Trust II is 330 N. Wabash Ave, Suite 3500, Chicago, IL 60611.
- (6) Consists of shares of common stock issuable upon the deemed conversion of the convertible preferred stock held by Novo Holdings A/S, or Novo. The board of directors of Novo, which is currently comprised of Jeppe Christiansen, Steen Riisgaard, Lars Rebien Sørensen, Jean-Luc Butel, Viviane Monges and Francis Cuss, has shared voting and investment power with respect to the shares held by Novo and may exercise such control only with the support of a majority of the members of the Novo board of directors. As such, no individual member of the Novo board of directors is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo. Dr. Edwards, a member of our board of directors, is employed as a Senior Partner at Novo Holdings A/S. The address of Novo Holdings A/S is Tuborg Havnevej 19, DK 2900 Hellerup, Denmark.

- (7) Consists of shares of common stock issuable upon the deemed conversion of the convertible preferred stock held by QSIP LP, or the QSIP Shares. Pursuant to an investment management agreement, QSIP LP and certain affiliates have delegated sole voting and dispositive power over the QSIP Shares to Newlight Partners LP. The general partner of Newlight Partners LP is Newlight GP LLC. The sole members of Newlight GP LLC are Ravi Yadav and David Wassong.
- (8) venBio Global Strategic GP II, L.P., or the General Partner, is the sole general partner of venBio Global Strategic Fund II LP, or venBio. venBio Global Strategic GP II, Ltd., or GP Ltd., is the sole general partner of the General Partner. Robert Adelman and Corey Goodman are directors of the GP Ltd. As the sole general partner of the Fund, the General Partner may be deemed to own beneficially the shares held by venBio, which consist of shares of common stock issuable upon the deemed conversion of the convertible preferred stock held by venBio. As the sole general partner of the General Partner, the GP Ltd. likewise may be deemed to own beneficially the shares held by venBio. As directors of the GP Ltd, each of the Directors likewise may be deemed to own beneficially the shares held by venBio. The address for venBio, the General Partner and GP Ltd. is c/o venBio Partners, LLC, 1700 Owens Street, Suite 595, San Francisco, CA 94158.

DESCRIPTION OF CAPITAL STOCK

General

At or prior to the consummation of this offering, we will file an amended and restated certificate of incorporation and we will adopt our amended and restated bylaws. Our amended and restated certificate of incorporation will authorize capital stock consisting of:

- shares of common stock, par value \$0.00001 per share; and
- shares of preferred stock, par value \$0.00001 per share.

We are selling shares of common stock in this offering (shares if the underwriters exercise their option to purchase additional shares of our common stock in full). All shares of our common stock outstanding upon consummation of this offering will be fully paid and non-assessable.

The following summary describes the material provisions of our capital stock. We urge you to read our amended and restated certificate of incorporation and our amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of common stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Upon our dissolution or liquidation, after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of shares of our common stock will be entitled to receive pro rata our remaining assets available for distribution for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

Preferred Stock

Upon the closing of this offering, (i) all outstanding shares of our convertible preferred stock will be automatically converted into shares of our common stock, (ii) all holders of our convertible preferred stock will be paid an accrued dividend in common stock in the aggregate amount of shares of our common stock and (iii) all outstanding shares of our redeemable preferred stock will automatically be cancelled.

Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Our Investors' Rights Agreement provides that certain holders of our preferred stock have certain registration rights as set forth below. The registration of shares of our common stock by the exercise of registration rights described below would enable the holders to sell these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts and commissions, stock transfer taxes, and fees and disbursements of counsel for any holder, except for the fees and disbursements of the selling holder counsel, of the shares registered by the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include. The demand, piggyback and Form S-3 registration rights described below will expire on the five-year anniversary of the closing of this offering, or with respect to any particular stockholder, such time after the closing of this offering that such stockholder can sell all of its shares entitled to registration rights under Rule 144 of the Securities Act during any 90-day period.

Demand Registration Rights

Any holder or holders of more than 50% of our common stock then outstanding converted from our convertible preferred stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of more than 50% of these shares may request that we register all or a portion of their shares on a Form S-1 registration statement; provided, that we are obligated to effect only five such registrations. Upon receipt of a request to file a Form S-1 registration statement, we must notify all other holders of our common stock converted from our convertible preferred stock and, within 60 days, file a Form S-1 registration statement under the Securities Act. We are not obligated to take any action to effect any registration during the period that is 60 days before our good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of, a registration statement initiated by us. Additionally, if our board of directors determines that it would be materially detrimental to us and our stockholders to effect such a registration, we have the right to defer such registration, not more than twice in any 12-month period, for a period of not more than 120 days.

Piggyback Registration Rights

In connection with this offering, pursuant to the Investors' Rights Agreement, each holder of each series of our convertible preferred stock was entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After the completion of this offering, in the event that we propose to register any of our

securities under the Securities Act, either for our own account or for the account of other security holders, the holders of common stock converted from our convertible preferred stock will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations. If a holder decides not to include all of its shares in any registration statement filed by us, it shall nevertheless continue to have the right to include its shares in any subsequent registration statement or registration statements as we may file with respect to offerings of our securities. We have the right to terminate or withdraw any registration initiated whether or not any holder has elected to include securities in such registration upon prompt notice to such holder or holders.

Form S-3 Registration

After the completion of this offering, any holder or holders of the common stock then outstanding converted from our convertible preferred stock will be entitled to certain Form S-3 registration rights. One or more holders of these shares may make a written request that we register the offer and sale of their shares on a registration statement on Form S-3 if we are eligible to file a registration statement on Form S-3. Upon receipt of a request to file a Form S-3 registration statement, we must notify all other holders of our common stock converted from our convertible preferred stock and, within 45 days, file a Form S-3 registration statement under the Securities Act. We are not obligated to take any action to effect any registration during the period that is 30 days before our good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a registration statement initiated by us. Additionally, if our board of directors determines that it would be seriously detrimental to us and our stockholders to effect such a registration, we have the right to defer such registration, not more than twice in any 12-month period, for a period of up to 120 days.

Forum Selection

Our amended and restated certificate of incorporation will provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery; or (iv) any action asserting a claim governed by the internal affairs doctrine. Unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock will be deemed to have notice of and consented to this provision.

Dividends

Declaration and payment of any dividend will be subject to the discretion of our board of directors. The time and amount of dividends will be dependent upon our business prospects, results of operations, financial condition, cash requirements and availability, debt repayment obligations, capital expenditure needs, contractual restrictions, covenants in the agreements governing our current and future indebtedness, industry trends, the provisions of Delaware law affecting the payment of distributions to stockholders and any other factors our board of directors may consider relevant. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business and to repay indebtedness, and therefore do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. See "Dividend Policy" and "Risk

Factors—Risks Related to this Offering and Ownership of our Common Stock—We have never paid dividends on our capital stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases."

Anti-Takeover Provisions

Our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect immediately prior to the consummation of this offering, will contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our board of directors the power to discourage acquisitions that some stockholders may favor. See "Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock."

Authorized but Unissued Shares

The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of Nasdaq. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Classified Board of Directors

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, with the classes as nearly equal in number as possible and each class serving three-year staggered terms. In all other cases and at any other time, directors may only be removed from our board of directors for cause by the affirmative vote of a majority of the shares entitled to vote. See "Management—Composition of our Board of Directors." These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes in control of us or our management.

Stockholder Action; Special Meeting of Stockholders

Our amended and restated certificate of incorporation will provide that our stockholders will not be able to take action by written consent for any matter and may only take action at annual or special meetings. As a result, a holder controlling a majority of our capital stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws, unless previously approved by our board of directors. Our amended and restated certificate of incorporation will further provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer, our president or another officer selected by a majority of our board of directors, thus limiting the ability of a stockholder to call a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

In addition, our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. In order for any matter to be "properly brought" before a meeting, a stockholder will have to comply with advance notice and duration of ownership requirements and provide us with certain information. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a qualified stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

Amendment of Certificate of Incorporation or Bylaws

The DGCL provides generally that the affirmative vote of the holders of a majority in voting power of the shares entitled to vote is required to amend a corporation's certificate of incorporation, unless a corporation's certificate of incorporation requires a greater percentage. Upon consummation of this offering, our bylaws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders a majority of the votes which all our stockholders would be eligible to cast in an election of directors.

Section 203 of the DGCL

We are subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Limitations on Liability and Indemnification of Officers and Directors

Our amended and restated bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL, along with the right to have expenses incurred in defending proceedings paid in advance of their final disposition. Prior to the consummation of this offering, we intend to enter into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification and advancement provisions contained under our amended and restated bylaws and provided under Delaware law. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders to recover monetary damages against a director for breach of fiduciary duties as a director.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Corporate Opportunity Doctrine

Delaware law permits corporations to adopt provisions renouncing any interest or expectancy in certain opportunities that are presented to the corporation or its officers, directors or stockholders. Our amended and restated certificate of incorporation will, to the maximum extent permitted from time to time by Delaware law, renounce any interest or expectancy that we have in, or right to be offered an opportunity to participate in, specified business opportunities that are from time to time presented to our officers, directors or certain of our stockholders or their respective affiliates, other than those opportunities our officers, directors, stockholders or affiliates are presented with while acting in their capacity as an employee, officer or director of us or our affiliates. Our amended and restated certificate of incorporation will provide that, to the fullest extent permitted by law, any director or stockholder who is not employed by us or our affiliates will not have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar lines of business in which we or our affiliates now engage or propose to engage; or (ii) otherwise competing with us or our affiliates. In addition, to the fullest extent permitted by law, if any director or stockholder, other than a director or stockholder who is employed by us or our affiliates acting in their capacity as an employee or director of us or our affiliates, acquires knowledge of a potential transaction or other business opportunity which may be a corporate opportunity for itself or himself or its or his affiliates or for us or our affiliates, such person will have no duty to communicate or offer such transaction or business opportunity to us or any of our affiliates and they may take any such opportunity for themselves or offer it to another person or entity. To the fullest extent permitted by Delaware law, no potential transaction or business opportunity may be deemed to be a corporate opportunity of ours or our subsidiary. Our amended and restated certificate of incorporation will not renounce our interest in any business opportunity that is expressly offered to an employee director, employee officer or employee in his or her capacity as a director, officer or employee of Harmony Biosciences Holdings, Inc.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders will have appraisal rights in connection with a merger or consolidation of Harmony Biosciences Holdings, Inc. Pursuant to the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such mergers or consolidations will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery, subject to certain limitations.

Stockholders' Derivative Actions

Under the DGCL, any of our stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, in certain circumstances. Among other things, either the stockholder bringing any such action must be a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock must have thereafter devolved by operation of law, and such stockholder must continuously hold shares through the resolution of such action.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is

Trading Symbol and Market

We have applied to list our common stock on the Nasdaq under the symbol "HRMY."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we have applied to have our common stock listed on the Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of shares of common stock, assuming the issuance of shares of common stock offered by us in this offering. Of these shares, all shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

Lock-Up Agreements

We, our officers and directors and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock will agree that, without the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Piper Sandler & Co., as representatives of the underwriters, we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus:

- offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly
 or indirectly or publicly disclose the intention to make any offer, sale, pledge or disposition of any shares of our common stock, or
 any options or warrants to purchase any shares of our common stock, or any securities convertible into, or exchangeable for, or
 that represent the right to receive, shares of our common stock; or
- enter into any swap or other arrangement that transfers to another, all or a portion of the economic consequences of ownership of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock,

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

The representatives of the underwriters have advised us that they have no present intent or arrangement to release any shares subject to a lock-up, and will consider the release of any lock-up on a case-by-case basis. Upon a request to release any shares subject to a lock-up, the representatives of the underwriters would consider the particular circumstances surrounding the request, including, but not limited to, the length of time before the lock-up expires, the number of shares requested to be released, reasons for the request, the possible impact on the market or our common stock and whether the holder of our shares requesting the release is an officer, director or other affiliate of ours.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least 180 days

would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- · 1% of the number of shares of our common stock then outstanding; and
- the average weekly trading volume in our common stock on the notice on Form 144 with respect to such sale.

 during the four calendar weeks preceding the filing of a

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

Under Rule 144, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of the registration statement of which this prospectus forms a part is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. Our affiliates can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Registration Rights

Pursuant to our Investor Rights Agreement, beginning six months after the completion of this offering, the holders of up to shares of our common stock, or certain transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. See the section titled "Description of Capital Stock—Registration Rights" for a description of these registration rights. If the offer and sale of these shares of our common stock are registered, the shares will be freely tradable without restriction under the Securities Act, subject to the Rule 144 limitations applicable to affiliates, and a large number of shares may be sold into the public market.

Registration Statements on Form S-8

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options, and common stock issuable, under our equity incentive plans. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date of this prospectus. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- · brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- · tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(I)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into
 account in an applicable financial statement.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable

withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below on information reporting, backup withholding and payments made to foreign accounts, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a non-resident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a

United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC. Jefferies LLC and Piper Sandler & Co. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Jefferies LLC	
Piper Sandler & Co.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to additional shares from us.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make internet distributions on the same basis as other allocations.

We and our executive officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common

stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Piper Sandler & Co. See the section of this prospectus titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list our common stock on the Nasdaq under the symbol "HRMY."

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq , in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$ million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities or instruments of the issuer (directly, as collateral securing other obligations or otherwise) or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

European Economic Area

In relation to each Member State of the European Economic Area (each, a "Member State"), no offer of shares of our Class A common stock may be made to the public in that Member State other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and us that it is a "gualified investor" as defined in the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5 of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a

nondiscretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Member State means the communication in any form and by means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase shares, the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed at qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged in with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an

invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority, or FINMA, as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended, or CISA, and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licensable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended, or CISO, such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, Chicago, Illinois. Goodwin Procter LLP, Boston, Massachusetts has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

EXPERTS

The consolidated financial statements of Harmony Biosciences Holdings, Inc. and its subsidiary as of and for the years ended December 31, 2019 and 2018 included in this prospectus and registration statement have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the registration statement, which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to substantial doubt that exists regarding the ability of the Company to continue as a going concern. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed with the registration statement. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits filed with the registration statement. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the SEC pursuant to the Exchange Act. These reports, proxy statements, and other information will be available on the website of the SEC referred to above.

We also maintain a website at www.harmonybiosciences.com, through which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessed through our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Harmony Biosciences Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Harmony Biosciences Holdings, Inc. (formerly Harmony Biosciences II, Inc.) and subsidiary (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company is experiencing difficulty in generating sufficient cash flow to meet its obligations and sustain its operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Chicago, Illinois April 10, 2020

We have served as the Company's auditor since 2017.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS (U.S. dollars in thousands except share and per share data)

	December 31, 2019		December 31, 2018	
ASSETS				
CURRENT ASSETS:		0.4.457		00 500
Cash and cash equivalents	\$	24,457	\$	83,523
Trade receivables, net		4,255		-
Inventory, net		1,088		-
Prepaid expenses		1,436		703
Other current assets		261		2,458
Total current assets		31,497		86,684
NONCURRENT ASSETS:				
Property and equipment, net		1,330		1,576
Restricted cash		750		500
Intangible asset, net		72,185		-
Other noncurrent assets		941		522
Total noncurrent assets		75,206		2,598
TOTAL ASSETS	\$	106,703	\$	89,282
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT	_			
CURRENT LIABILITIES:				
Trade payables	\$	6,360	\$	1,462
Accrued compensation	Ψ	7,917	Ψ	3,953
Accrued expenses		5,500		1,816
Other current liabilities		115		1,010
				7 221
Total current liabilities		19,892		7,231
NONCURRENT LIABILITIES:		207		202
Deferred rent		287		262
Long term debt, net		97,946		201
Other noncurrent liabilities	_	163		261
Total noncurrent liabilities		98,396		523
TOTAL LIABILITIES	\$	118,288	\$	7,754
COMMITMENTS AND CONTINGENCIES (Note 9)				
CONVERTIBLE PREFERRED STOCK				
Convertible preferred stock, net of placement costs				
Series A convertible preferred stock—\$1.00 stated value; 286,000,000 shares authorized;				
285,000,000 issued and outstanding at December 31, 2019; 286,000,000 shares authorized;				
285,000,000 issued and outstanding at December 31, 2018		348,203		313,299
Series B convertible preferred stock—\$1.25 stated value; 8,030,000 shares authorized;				
8,000,000 issued and outstanding at December 31, 2019; 8,030,000 shares authorized;				
8,000,000 issued and outstanding at December 31, 2018		12,023		10,902
Series C convertible preferred stock—\$1.96 stated value; 25,600,000 shares authorized;				
25,510,205 issued and outstanding at December 31, 2019		51,051		-
STOCKHOLDERS' DEFICIT:				
Common stock—\$0.00001 par value; 423,630,000 shares authorized; 63,974,066 issued and				
outstanding at December 31, 2019; 398,030,000 shares authorized; 63,888,876 issued and				
outstanding at December 31, 2018		1		1
Accumulated deficit		(422,863)		(242,674)
TOTAL STOCKHOLDERS' DEFICIT		(422,862)		(242,673)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT	\$	106,703	\$	89,282
		_00,.00		30,232

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (U.S. dollars in thousands except share and per share data)

	Year Ended December 31,				
		2019		2018	
Net product revenues	\$	5,995	\$	-	
Cost of product sales		1,577		-	
Gross profit		4,418		-	
Operating expenses:					
Research and development		69,595		12,372	
Sales and marketing		44,318		16,861	
General and administrative		36,409		12,206	
Total operating expenses		150,322		41,439	
Operating loss		(145,904)		(41,439)	
Interest (expense) income, net		(6,073)		1,541	
Loss before income taxes		(151,977)		(39,898)	
Income taxes		<u>-</u>			
Net loss and comprehensive loss	\$	(151,977)	\$	(39,898)	
Accumulation of yield on preferred stock		(35,231)		(30,185)	
Net loss available to common stockholders	\$	(187,208)	\$	(70,083)	
LOSS PER SHARE:					
Loss per share, basic and diluted	\$	(2.93)	\$	(0.96)	
Weighted average number of shares of common stock, basic and diluted	6	3,891,677	72	2,765,366	

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (U.S. dollars in thousands except share and per share data)

	Convertible F Stock Series A, I Shares	k	Common Shares (1)	Stock Amount	Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
Balance as of December 31, 2017	270.000.000	\$266.750	77,221,876	\$ 1		\$ (168,020)	\$ (168,019)
Net loss	-	-	-	· -	-	(39,898)	(39,898)
Issuance of Series A convertible preferred stock, net of issuance cost	15,000,000	14,913	-	_	_	-	-
Issuance of Series B convertible preferred stock, net of issuance cost	8,000,000	9,905	-	-	-	-	-
Repurchase and cancellation of common shares	_	_	(13,333,000)	_	_	(3,200)	(3,200)
Preferred stock dividend, Series A	-	29,207	-	-	(1,079)	(28,128)	(29,207)
Preferred stock accretion, Series A	-	2,431	-	-	-	(2,431)	(2,431)
Preferred stock dividend, Series B	-	978	-	-	-	(978)	(978)
Preferred stock accretion, Series B	-	19	-	-	-	(19)	(19)
Stock-based compensation	-	-	-	-	1,079	-	1,079
Balance as of December 31, 2018	293,000,000	\$324,201	63,888,876	\$ 1	\$ -	\$ (242,674)	\$ (242,673)
Net loss	-	-	-	-	-	(151,977)	(151,977)
Issuance of Series C convertible preferred stock, net of issuance cost	25,510,205	48.868					
Preferred stock dividend. Series A	23,310,203	32.160	_	_	(9,994)	(22,166)	(32,160)
Preferred stock accretion, Series A	_	2,742	_	_	(3,334)	(2,742)	(2,742)
Preferred stock dividend, Series B	_	1.098	_	_	_	(1,098)	(1,098)
Preferred stock accretion, Series B	_	22	_	_	_	(22)	(22)
Preferred stock dividend, Series C	-	1,973	-	-	-	(1,973)	(1,973)
Preferred stock accretion, Series C	-	211	-	-	-	(211)	(211)
Exercise of Options	-	-	85,190	-	85	-	` 85 [°]
Stock-based compensation	-	-	-	-	9,909	-	9,909
Balance as of December 31, 2019	318,510,205	\$411,275	63,974,066	\$ 1	\$ -	\$ (422,863)	\$ (422,862)

⁽¹⁾ Common stock of Harmony Bioscience Holdings, Inc.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS (U.S. dollars in thousands except share and per share data)

	Year Ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(151,977)	\$ (39,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	395	184
Intangible amortization	2,815	-
Milestones associated with acquired in-process research & development (IPR&D)	52,000	4 070
Stock-based compensation expense	9,909	1,079
Noncash paid-in-kind interest expense	2,538	-
Debt issuance costs amortization	592	-
Change in operating assets and liabilities:	(4.055)	
Trade receivables	(4,255)	-
Inventory	(1,088)	(2.500)
Prepaid expenses and other assets Other non-current assets	1,467	(2,589)
	(420)	(522)
Trade payables	4,898	(610)
Accrued expenses and other liabilities Other non-current liabilities	7,763	3,033 524
	(73)	
Net cash used in operating activities	(75,436)	(38,799)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(149)	(1,342)
Milestone associated with acquired in-process research & development (IPR&D	(52,000)	-
Milestone and acquisition of intangible asset	(75,000)	
Net cash used in investing activities	(127,149)	(1,342)
CASH FLOWS FROM FINANCING ACTIVITIES:	·	
Proceeds from issuance of preferred stock	50,000	25,000
Preferred stock issuance costs	(1,132)	(185)
Repurchase of common stock	` <u>-</u>	(3,200)
Proceeds from long term debt	100,000	` -
Debt issuance costs	(5,184)	-
Proceeds from exercised options	85	-
Net cash provided by financing activities	143,769	21,615
NET DECREASE IN CASH	(58,816)	(18,526)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	84,023	102,549
		\$ 84.023
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	<u>\$ 25,207</u>	<u>Φ 04,023</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	\$ 4,230	\$ -
Cash paid during the year for milestones	127,000	
Supplemental Disclosures of Noncash Investing and Financing Activities:	\$ 32,160	\$ 29,207
Series A Preferred Stock accrued return		
Series A accretion of issuance costs	2,742	2,431
Series B Preferred Stock accrued return	1,098	978
Series B accretion of issuance costs	22	20
Series C Preferred Stock accrued return	1,973	-
Series C accretion of issuance costs	211	-

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of and for the years ended December 31, 2019 and 2018 (U.S. dollars in thousands except share and per share data)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Our operating subsidiary, Harmony Biosciences, LLC, was formed on May 17, 2017. Harmony Biosciences Holdings, Inc. (the "Company") was founded on July 25, 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and the Company converted to a Delaware corporation named Harmony Biosciences II, Inc. on September 19, 2017. On February 3, 2020, the Company changed its name to Harmony Biosciences Holdings, Inc. The Company is a holding company and has no operations. The Company's operations are conducted in its wholly owned subsidiary, Harmony Biosciences, LLC ("Harmony"). Harmony is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients suffering from rare central nervous system disorders living with unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

2. GOING CONCERN

The consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred operating losses and negative cash flows from operations since inception. As of December 31, 2019, and 2018, the Company has an accumulated deficit of \$422,863 and \$242,674, respectively. Management expects to continue to incur operating losses and negative cash flows from operations in 2019. In addition, as more fully described in Note 6, the Company is subject to milestone payments associated with a license agreement, of which \$127,000 were triggered in 2019 with other potential milestones of \$142,000 yet to be triggered. The Company has financed its operations to date with proceeds from the sale of preferred securities.

The Company will need to raise additional capital in order to continue to fund operations, including milestone obligations under its licensing agreement. The Company believes that it will be able to obtain additional capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

Accordingly, these factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All intercompany accounts and transactions have been eliminated in consolidation.

Significant Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to, the results of clinical testing and trial activities of the Company's product candidates; the Company's ability to obtain regulatory approval to market its products; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, the Company's products, if approved; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its product candidates; and the Company's ability to raise capital.

The Company currently has one commercially approved product, WAKIX®, and there can be no assurance that the Company's research and development and clinical trials will result in any successfully commercialized products in addition to WAKIX®. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Operating Segments

Harmony holds all its tangible assets, conducts its operations, and revenues are generated in the U.S. Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Makers (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company has determined it operates in a single operating segment and has one reportable segment.

Fair Value of Financial Instruments

The Company's consolidated financial statements include cash, cash equivalents, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value.

It is the Company's policy, in general, to measure nonfinancial assets and liabilities at fair value on a nonrecurring basis. The instruments are not measured at fair value on an ongoing basis, but are subject to fair value adjustments in certain circumstances (such as evidence of impairment), which, if material, are disclosed in the accompanying footnotes.

The Company measures certain assets and liabilities at fair value in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy that serves to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would

use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3—Valuations based on unobservable inputs and models that are supported by little or no market activity.

The Company's financial assets which are measured at fair value on a recurring basis were comprised of cash, cash equivalents, and restricted cash of \$25,207 and \$84,023 at December 31, 2019 and 2018, respectively, based on Level 1 inputs.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash and, if applicable, highly liquid investments with an original maturity of three months or less when purchased, including investments in Money Market Funds. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	As of Dec	ember 31,
	2019	2018
Cash and cash equivalents	\$24,457	\$83,523
Restricted cash	750	500
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$25,207	\$84,023

Amounts included in restricted cash represent those amounts required to be held as a security deposit in the form of letters of credit for the Company's credit card program.

Concentrations of Risk

Substantially all of the Company's cash and money market funds are held with a single financial institution. Due to its size, the Company believes this financial institution represents minimal credit risk. Deposits in this institution may exceed the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation for U.S. institutions. The Company has not experienced any losses on its deposits of cash and cash equivalents. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

We are also subject to credit risk from our trade receivables related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to specialty pharmaceutical distribution companies within the U.S. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced credit losses on our accounts receivable. As of December 31, 2019, two customers accounted for 91% of gross accounts receivable, Caremark LLC, or CVS Caremark, which accounted for 72% of gross accounts receivable, and PANTHERx Specialty Pharmacy LLC, or Pantherx, which accounted for 19% of gross accounts receivable. For the year ended December 31, 2019 two customers accounted for 88% of gross product revenues, CVS Caremark accounted for 59% of gross product revenues and Pantherx accounted for 29% of gross product revenues.

We depend on a single source supplier for our product, product candidates and their active pharmaceutical ingredient.

Inventory

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If our estimate of future demand changes, we consider the impact on the reserve for excess inventory and adjust the reserve as required. Increases in the reserve are recorded as charges in cost of product sales.

We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval. We did not capitalize preapproval inventory during 2019 or 2018.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and ten years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. The Company's leasehold improvements primarily relate to its new corporate headquarters in Plymouth Meeting, PA, and are generally being amortized through the end of the lease term in July 2024. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations and comprehensive loss in the period realized.

Intangible Asset

Intangible assets with finite useful lives consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Such assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

Accrued Compensation

The Company accrues for liabilities under discretionary employee and executive bonus plans. These estimated compensation liabilities are based on progress against corporate objectives approved by the Company's board of directors, compensation levels of eligible individuals, and target bonus percentage levels. The board of directors reviews and evaluates the performance against these objectives and ultimately determines what discretionary payments are made. As of December 31, 2019, and 2018, the Company accrued approximately \$7,917 and 3,953, respectively, for liabilities associated with these employee and executive bonus plans.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by collaboration partners and third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses and other current liabilities on the balance sheets and within research and development expense on the statement of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its collaboration partners and third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Leases

The Company leases office space and recognizes related rent expense on a straight-line basis over the term of the lease. The Company has negotiated certain landlord/tenant incentives, rent holidays and escalations in the base price of rent payments under operating leases. The Company recognizes these incentives, rent holidays and rent escalations on a straight-line basis over the lease term. Deferred rent balances are classified as current or noncurrent in the balance sheet based upon the period when reversal of the liability is expected to occur.

Convertible Preferred Stock

Preferred securities that are redeemable for cash or other assets are to be classified outside of permanent equity if they are redeemable (1) at a fixed or determinable price on a fixed or determinable date, (2) at the option of the holder, or (3) upon the occurrence of an event that is not solely within the issuer's control. The holders of convertible preferred stock have the right to redeem such stock based on the passage of time and as a result are probable of becoming redeemable. As such, the Company concluded its convertible preferred stock should be classified as temporary equity. The redemption amount at each balance sheet date also includes amounts representing dividends not currently declared or paid, but which will be payable under the redemption and should be recognized as part of the instrument's carrying value (see Note 10 for further detail).

Revenue Recognition

Effective January 1, 2019, the Company adopted ASC 606, *Revenue from Contracts with Customers (ASC 606)*. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At

contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determine those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. The Company has determined that the delivery of its product to its customer constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore, no amount of consideration has been allocated as a financing component. Taxes collected related to product sales are remitted to governmental authorities and are excluded from revenue.

Product Sales, Net

The Company began commercial sales of WAKIX® in November 2019. The Company sells WAKIX® to its customers (a limited number of specialty distributors) that, in turn, distribute WAKIX® to patients.

The Company recognizes revenue on sales of WAKIX® when the customer obtains control of the product, which occurs at a point in time, typically upon delivery. Product revenues are recorded at the product's wholesale acquisition costs, net of applicable reserves for variable consideration that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the sale of WAKIX®. Components of variable consideration include government and commercial contracts, product returns, commercial co-payment assistance program transactions, and distribution services fees. These deductions are based on the amounts earned or to be claimed on the related sales, and are classified as a current liability or reduction of receivables, based on expected value method and a range of outcomes and are probability weighted in accordance with ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognition under contracts will not occur in a future period. The Company's analyses contemplate the application of the constraint in accordance with ASC 606. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from its estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Cost of Product Sold

Cost of product sales include manufacturing and distribution costs, the cost of drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, and salaries of employees involved with production. The Company began capitalizing inventory upon FDA approval of WAKIX® with a portion of the inventory sold during the year produced prior to FDA approval and, therefore, expensed \$1,323 previously as research and development expense in 2019. Excluded from cost of product sales shown on the consolidated statements of operations and comprehensive loss is amortization of acquired developed technology of \$2,815 in 2019.

Research and Development Expenses

Research and development costs are expensed as incurred. Liabilities due to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred.

Upfront payments and pre-FDA approval milestone payments made for licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods and services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expense was \$7,072 in 2019.

Stock-Based Compensation

The Company recognizes compensation expense relating to stock-based payment transactions in operating results using a fair value measurement method, in accordance with FASB ASC 718, *Compensation-Stock Compensation*. ASC 718 requires all stock-based payments to employees to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. The vesting period has a time-based provision consisting of a five-year period, with 20% vesting on each anniversary of the vesting start date. Upon a change of control, any unvested awards will immediately vest. The Company determines the fair value of stock-based awards using the Black-Scholes option-pricing model, which uses both historical and current market data to estimate fair value. The method incorporates various assumptions, such as the risk-free interest rate, expected volatility, expected dividend yield, and expected life of the options.

On January 1, 2019, the Company early adopted and accounts for stock-based payments granted to nonemployees in accordance with ASU 2018-07, Compensation – Stock Compensation (ASC 718): Improvements to Nonemployee Share – Based Payment Accounting. The Company determines the fair value of the stock-based payment as the fair value of the equity instruments issued. It is measured on the grant date.

The Company also has nonemployee stock awards subject to a performance condition that are recognized based on probable outcome. As of December 31, 2018, the Company determined that the performance condition was not probable. On November 15, 2019 the Company modified the award to remove the performance condition resulting in \$8,400 of noncash expense that is included in the Company's consolidated results of operations for the year ended December 31, 2019 (see Note 13 for further details).

Basic and Diluted Loss per Share

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Diluted net income per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. The computation of diluted net loss per shares does not include the conversion of securities that would have an anti-dilutive effect. The basic and diluted computations of net loss per share for the Company are the same because the effects of the Company's convertible securities would be anti-dilutive (see Note 15 for further detail).

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases

and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Deferred tax assets may be reduced by a valuation allowance if, based on all available evidence, it is more likely than not that some portion or all of the deferred income tax assets will not be realized. Management judgment is required in determining the period in which a reversal of a valuation allowance should occur. The Company is required to consider all available evidence, both positive and negative, such as historical levels of income and future forecasts of taxable income among other items, in determining whether a full or partial release of its valuation allowance is required. The Company's accounting for deferred tax consequences represents the best estimate of those future events. The Company presents deferred income taxes on the Consolidated Balance Sheet on a jurisdictional basis as either a net noncurrent asset or liability.

The Company recognizes the effect of income tax positions only if those positions are more likely than not sustainable, based solely on its technical merits and consideration of the relevant taxing authority's widely understood administrative practices and precedents. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which a change in judgment occurs. At December 31, 2019 and 2018, the Company did not have any unrecognized uncertain tax positions. The Company's policy is to include any interest and penalties as a component of income tax expense.

Debt Issuance Costs

Debt issuance costs are reported at cost, less accumulated amortization and are presented in the consolidated balance sheet as a direct deduction from the carrying value of the associated debt. The related amortization expense is included in interest expense, net in our consolidated statements of operations and comprehensive loss.

Comprehensive Loss

The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Subsequent Events

The Company has evaluated and, as necessary, made changes to these consolidated financial statements for subsequent events through April 10, 2020, the date these consolidated financial

statements were available to be issued. All subsequent events that provided additional evidence about conditions existing at the date of the consolidated statements of financial position were incorporated into the consolidated financial statements (see Note 17 for further detail).

Recently Issued Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, with amended guidance that simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for forfeitures, as well as classification in the statement of cash flows. Since inception the Company has elected early adoption of ASU No. 2016-09 to recognize forfeitures as they occur.

In February 2016, the FASB issued amended guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities in the balance sheet and disclosing key information about leasing arrangements. The new guidance clarifies the criteria for distinguishing between a finance lease and operating lease, as well as classification between the two types of leases, which is substantially unchanged from the previous lease guidance. Further, the new guidance requires a lessee to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset, initially measured at the present value of the lease payments. For finance leases, a lessee should recognize interest on the lease liability separately from amortization of the right-of-use asset. For operating leases, a lessee should recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election not to recognize lease assets and lease liabilities. The new standard will become effective for the Company's fiscal year ending December 31, 2021. The Company is currently assessing the impact of this amended quidance and the timing of adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 for companies deemed to be small reporting companies as of November 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact of adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU No. 2016-15 provides specific guidance on eight cash flow issues where current guidance is unclear or does not include any specifics on classification, including contingent consideration payments made after a business combination and distributions received from equity method investees, among other items. The Company has adopted this standard with an immaterial impact to its consolidated statements of cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* This standard requires entities to show the changes in the total of cash, cash equivalents, restricted cash, and restricted cash equivalents in the statement of cash flows and no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. Since inception, the Company has early adopted the provisions of this ASU, with such provisions reflected in the consolidated statements of cash flows.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share – Based Payment Accounting. The amended

guidance is meant to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, including, but not limited to, forfeitures, measurement date, and term used for measurement date. The Company has adopted this standard with an immaterial impact to its consolidated balance sheets and statement of operations and comprehensive loss.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other – Internal-Use Software (Topic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amended guidance requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC-350-40, Intangibles—Goodwill and Other—Internal-Use Software, to determine which implementation costs to capitalize as an asset. The Company has elected early adoption of ASU No. 2018-15 with such provisions resulting in an immaterial impact reflected in the consolidated balance sheets and statement of operations and comprehensive loss.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual reporting periods beginning after December 15, 2020 with early adoption permitted. The Company is currently evaluating the impact of adopting this new accounting guidance.

4. INVENTORY

Inventory, net consisted of the following:

	As	of
	Decem	ber 31,
	2019	2018
Raw materials	\$ 384	\$ -
Work in process	417	-
Finished goods	287	
Total inventory, net	\$1,088	\$ -

5. INTANGIBLE ASSET

On August 15, 2019, the Company received FDA approval of WAKIX® (pitolisant) for the treatment of EDS in adult patients with narcolepsy. This event triggered a milestone payment of \$75,000 associated with its license agreement with Bioprojet which the Company capitalized as an intangible asset. The Company determined a useful life of 10 years and as of December 31, 2019 the remaining useful life was 9.75 years. Prior to this event all other milestones associated with the license agreement were expensed through research and development as they did not meet the criteria to recognize as an intangible asset.

The gross carrying amount and net book value of the intangible asset is as follows:

	r 31,
2019	2018
Gross Carrying Amount \$75,000	\$ -
Accumulated Amortization (2,815)	
Net Book Value \$72,185	\$ -

6. LICENSE AGREEMENTS

On July 28, 2017, Harmony entered into a License and Commercialization Agreement (the "Agreement") with Bioprojet Societe Civile de Recherche ("Bioprojet") whereby Harmony acquired the exclusive right to commercialize the pharmaceutical compound pitolisant for the treatment, and/or prevention, of narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, and Parkinson's disease as well as any other indications unanimously agreed by the parties in the United States and its territories. The Agreement called for an initial license payment of \$150,000, which was recorded to research and development expense in the consolidated statement of operations and comprehensive loss for the period from May 17, 2017 (inception) to December 31, 2017. A milestone of \$50,000 was due upon acceptance by the FDA of pitolisant's New Drug Application (NDA), which was achieved on February 12, 2019 and was expensed within research and development for the year ended December 31, 2019. In addition, a milestone of \$77,000, including a \$2,000 fee, was due upon FDA approval of WAKIX® (pitolisant) for treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy, which was achieved on August 15, 2019. The Agreement also requires sales-based milestones, a fixed trademark royalty and a tiered royalty, all based on net sales, which becomes due and payable to Bioprojet on a quarterly basis with an additional milestone of \$102,000 due upon FDA approval of other specific indications and \$40,000 due upon reaching specific sales milestone. For the year ended December 31, 2019, the Company has accrued \$938 for sales-based, trademark and tiered royalties.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

		As of	
		December 31,	
	2019	2018	
Professional fees, consulting, and other services	\$1,404	\$1,434	
Selling and marketing	1,547	-	
Royalties due to third parties	938	-	
Rebates and other sales deductions	713	-	
Debt issuance costs	638	313	
Employee travel and other expenses	260	69	
	\$5,500	\$1,816	

8. DEBT

Series A Debt Conversion

On July 27, 2017, in connection with the Bioprojet Agreement described in Note 6, the Company entered into an agreement to issue an 8% convertible note in an aggregate of \$150,000 in principal amount, whereby \$100,000 of the principal could be settled through exchange for the issuance of preferred securities of Harmony Biosciences II, LLC upon consummation of an equity financing transaction. In addition, upon consummation of an equity financing transaction, holders of the notes would be issued warrants to purchase common units representing a total of 4% of the issued and outstanding common units determined on an "as converted" basis.

As part of the September 22, 2017 \$270,000 Series A convertible preferred stock raise, as described in Note 10, the Company exchanged \$100,000 of the original \$150,000 principal amount into Series A convertible preferred stock and repaid, in cash, \$50,000 of the remaining principal balance and any accrued interest on the notes through this date.

Credit Agreement

On February 28, 2019, the Company entered into a multi-draw loan agreement with CRG Servicing LLC for an aggregate of \$200,000 (the "Loan"), which matures in March 2025. The Loan bears a fixed rate of 12%. The Loan agreement requires compliance with certain financial covenants. The Company can draw three tranches of the Loan based on achieving specific milestones and dates. The Company may elect to pay the interest on the outstanding principal amount as follows: (i) only 7.5% of the 12% per annum in cash, paid quarterly, starting in March 2019, and (ii) 4.5% of the 12% per annum interest as compounded interest, added to the aggregate outstanding principal balance quarterly; the amount of any such compounded interest being a paid-in-kind loan.

As of December 31, 2019 the Company had borrowed \$100,000, resulting in cash proceeds received of \$94,816, net of issuance costs. The issuance costs of \$5,184 are being amortized over the six year life of the Loan resulting in \$592 of issuance costs being amortized through interest expense for the year ended December 31, 2019. Unamortized debt issuance costs as of December 31, 2019 are \$4,592 and are presented in the consolidated balance sheets as a direct deduction from the carrying value of the debt.

For the year ended December 31, 2019, interest expense associated with the principal of the Loan consisted of \$6,768, of which \$4,230 was paid in cash and \$2,538 was added to the aggregate outstanding principal balance.

9. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company is subject to claims and suits arising in the ordinary course of business. The Company accrues for such liabilities when they are known if they are deemed probable and can be reasonably estimated.

During 2018 and 2019 the Company had an ongoing litigation with the former chief executive officer related to the value and arbitration of vested common shares. On October 24, 2019 the Company reached a settlement resulting in \$3,466 of general and administrative expense reflected in the Company's consolidated results of operations for the year ended December 31, 2019.

Lease Agreements

In April 2018, the Company entered into an operating lease for approximately nine thousand square feet of office space in Northbrook, IL, which expires in January 2020.

In June 2018, the Company entered into an operating lease for approximately seven thousand square feet of office space in Plymouth Meeting, PA, which expires in April 2024.

In November 2019, the Company entered into an operating lease for approximately four thousand square feet of office space in Chicago, IL, which expires in December 2020.

The terms of the lease payments provide for rental payments on a monthly basis and on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. In addition, tenant improvement allowances recorded are amortized as a reduction to rent expense on a straight-line basis over the lease term. Rent expense was \$1,051 and \$381 for the year ended December 31, 2019 and 2018, respectively.

The following table sets forth the lease payment obligations as of December 31, 2019, for the periods indicated below:

Years ending December 31,	
2020	\$ 726
2021	443
2022	443
2023	443
2024	148
Thereafter	-
Total	\$2,203

10. CONVERTIBLE PREFERRED STOCK

Series A Preferred Stock

On September 22, 2017, the Company issued 270,000,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$270,000 in the aggregate. On January 8, 2018, the Company issued an additional 15,000,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$15,000 in the aggregate. As of December 31, 2019, and 2018, there were 286,000,000 Series A convertible preferred stock authorized of which 285,000,000 were issued and outstanding. Each outstanding share of Series A convertible preferred stock accrues dividends at 10% per annum of the Series A original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series A convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return was \$68,764 and \$36,604 at December 31, 2019 and 2018, respectively. For the period ended December 31, 2019, and 2018, accretion of issuance costs of \$2,742 and \$2,431, respectively, was recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$5,561 and \$8,305, respectively, are recorded as a direct reduction of Series A convertible preferred stock in the Company's consolidated balance sheef.

Series B Preferred Stock

On January 8, 2018, the Company issued 8,000,000 shares of Series B convertible preferred stock for a purchase price of \$1.25 per share, or \$10,000 in the aggregate. As of December 31, 2019 and 2018, there were 8,030,000 shares of Series B convertible preferred stock authorized, of which 8,000,000 were issued and outstanding. Each outstanding share of Series B convertible preferred stock accrues dividends at 10% per annum of the Series B original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series B convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return was \$2,076 and \$978 at December 31, 2019 and 2018, respectively. For the period ended December 31, 2019 and 2018, accretion of issuance costs of \$22 and \$20, respectively, was recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$53 and \$75, respectively, are recorded as a direct reduction of Series B convertible preferred stock in the Company's consolidated balance sheet.

Series C Preferred Stock

On August 9, 2019, the Company issued 25,510,205 shares of Series C convertible preferred stock for a purchase price of \$1.96 per share, or \$50,000 in the aggregate. As of December 31, 2019 there were 25,600,000 shares of Series C convertible preferred stock authorized, of which 25,510,205 were issued and outstanding. Each outstanding share of Series C convertible preferred stock accrues

dividends at 10% per annum of the Series C original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series C convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return was \$1,973 at December 31, 2019. As of December 31, 2019, accretion of issuance costs of \$211 was recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$921 are recorded as a direct reduction of Series C convertible preferred stock in the Company's consolidated balance sheet.

Redemption

The holders of a majority of the issued and outstanding Series A, Series B, and Series C convertible preferred stock may require that the Company redeem all of the issued and outstanding shares of Series A, Series B, and Series C convertible preferred stock at any time on or after September 22, 2021. The per share redemption price will be equal to the Series A original issue price for the Series B convertible preferred stock, the Series B original issue price for the Series B convertible preferred stock, plus, in each case, the amount of accrued and unpaid preferred dividends with respect to such shares.

Optional Conversion Rights

Each share of Series A, Series B, and Series C convertible preferred stock is convertible, at any time at the option of the holder, into such number of fully paid shares of common stock as is determined by dividing (x) the applicable original issuance price by (y) the conversion price in effect at the time of conversion. Accordingly, each share of Series A, Series B, and Series C convertible preferred stock is convertible into common stock on a one-for-one basis. Each applicable conversion price is subject to adjustment for any stock dividends, stock splits or stock combinations, reclassifications or exchanges of similar stock, upon a reorganization, merger or consolidation of the Company, or upon the issuance or sale by the Company of common stock for consideration less than the applicable conversion price.

Mandatory Conversion Rights

Each share of Series A, Series B, and Series C convertible preferred stock will automatically convert into the number of shares of common stock determined in accordance with the conversion rate applicable to optional conversions, as described above, upon the closing of the sale of shares of the Company's common stock to the public at a price of at least \$2.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$100,000 of gross proceeds, net of underwriting discounts and commissions, to the Company.

Dividends

The holders of Series A, Series B, and Series C convertible preferred stock are entitled to receive, when and if declared by the board of directors of the Company, cumulative dividends equal to a 10% per annum of Series A, Series B, and Series C convertible preferred stock. In addition, the holders of the outstanding shares of Series A, Series B, and Series C convertible preferred stock are entitled to receive, when and if declared by the board of directors of the Company, a dividend at least equal to any dividend payable on the Company's common stock as if all convertible preferred stock had been converted to common stock. No dividends have been declared as of December 31, 2019 and 2018.

Liquidation

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Series A, Series B, and Series C convertible preferred stock shall be entitled to receive pro rata, prior and in preference to any distribution to the holders of the common stock, an amount equal to the greater of (i) the original issuance prices of each series (in each case, as adjusted for stock splits, stock dividends or distributions, recapitalizations, and similar events) and all accrued but unpaid dividends, if any or (ii) such amount per share as would have been payable had all shares of Series A, Series B, and Series C convertible preferred stock been converted to common stock. If the assets and funds to be distributed among the holders of convertible preferred stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Voting Rights

Each share of convertible preferred stock has a number of votes equal to the number of shares of common stock into which it is convertible. The holders of convertible preferred stock, voting together as a single class, shall be entitled to elect six members of the Company's board of directors. The holders of common stock have the right to elect two members of the Company's board of directors. With respect to any other matter presented to the stockholders for their consideration or action at any meeting of the board of directors, the holders of the Series A, Series B, and Series C convertible preferred stock are entitled to cast the number of votes equal to the number of whole shares of common stock into which such preferred shares are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of the Series A, Series B, and Series C convertible preferred stock are entitled to vote together with the holders of common stock as a single class. In addition, certain matters, prior to being able to be undertaken by the Company, require the approval of a majority of the holders of the Company's convertible preferred stock, voting as a separate class.

11. STOCKHOLDERS' DEFICIT

Common Stock

On September 19, 2017, Harmony Biosciences II, LLC was converted to a C corporation named Harmony Biosciences II, Inc., at which point 63,333,000 of outstanding common units were converted to 63,333,000 of common shares.

On September 22, 2017, the Company issued 13,888,870 warrants, with an exercise price of \$0.01 per share, to the holders of the 8% convertible notes upon the consummation of an equity financing transaction and these warrants were immediately exercised resulting in the issuance of 13,888,870 common shares and proceeds of \$139.

On August 31, 2018, the Company repurchased and canceled 13,333,000 of common shares from the former chief executive officer for \$3,200.

As of December 31, 2019 and 2018 there were 423,630,000 and 398,030,000 common shares authorized, respectively, of which 63,974,066 and 63,888,876 were issued and outstanding, respectively. After the preferences of the preferred stock are paid, distributions are made to the holders of the common shares.

Holders of common shares are entitled to one vote for each share of common stock held. Holders of common shares have voting privileges with respect to the election of two of the eight directors of the

board of directors of the Company, and any other matter presented to the shareholders for their consideration or action at any meeting of the board of directors. Holders of common shares may not vote on amendments to the Company's Certificate of Incorporation that relate solely to the terms of one or more outstanding Series of preferred stock if the holders of such affected Series are entitled, either separately or together with the holders of one or more other such Series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law.

10,000,000 common shares held by an investor were subject to certain forfeiture provisions that are dependent upon the outcome of certain future events. On November 15, 2019 the Company removed the provision associated with this forfeiture resulting in \$8,400 of noncash stock compensation expense reflected in the Company's consolidated results of operations for the year ended December 31, 2019. For the year ended December 31, 2018 no expense has been reflected in the Company's consolidated results of operations.

12. REVENUES

The following table presents a summary of total net revenues:

	Year i	Year Ended	
	Decem	December 31,	
	2019	2018	
Wakix®	\$5,995	\$ -	
Total	5,995		

13. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

Stock Incentive Plan

On August 7, 2017, the Company adopted an equity incentive plan (the "Plan"). Under the Plan, directors, officers, employees, consultants, and advisors of the Company can be paid incentive compensation measured by the value of the Company's common shares through grants of stock options, stock appreciation rights, or restricted stock.

Awards under the Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement (generally five years from the date of grant), at achievement of a performance requirement, or upon change of control (as defined in the applicable plan).

Changes in stock options granted under the Plan as of December 31, 2019 and 2018, are as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Awards outstanding—December 31, 2018	16,365,283	\$ 1.00	9.07
Stock options issued	3,770,000	\$ 1.00	
Stock exercised	(85,190)	\$ 1.00	
Stock options forfeited	(536,984)	\$ 1.00	
Awards outstanding—December 31, 2019	19,513,109	\$ 1.00	8.33

As of December 31, 2019 and 2018, 4,708,003 and 1,535,137, respectively, options issued under the Plan were vested. The Company has elected early adoption of ASU No. 2016-09 to recognize

forfeitures as they occur. As a result of the adoption, for the years ended December 31, 2019 and 2018, the Company reversed \$4 and \$10, respectively, of stock-based compensation previously recorded.

Value of Stock Options

The Company has valued awards for each of the plans included herein using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on historical volatility of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for the time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The assumptions used to value the awards are summarized in the following table.

	2019	2018
Dividend yield	0.00%	0.00%
Expected volatility	95.30 - 99.30%	122.00%
Risk-free interest rate	1.60 - 2.59%	2.39%
Lack of marketability discount	26.00 - 31.00%	43.00%
Expected term (years)	6.5	6.5

The weighted average per share fair market value of awards issued under the Plan was \$0.42 and \$0.40 in 2019 and 2018, respectively.

Stock-based compensation expense was \$9,909, including \$8,400 discussed in Note 11, and \$1,079 for the year ended December 31, 2019 and 2018, respectively, and was recorded in the consolidated statement of operations and comprehensive loss in the following line items:

		Year Ended December 31,	
	2019	2018	
Research and development expense	\$ 287	\$ 209	
Sales and marketing expense	351	415	
General and administrative expense	9,271	455	
	\$9,909	\$1,079	

Awards issued under the Plan are reflected as a component of equity in these consolidated financial statements. The Company will recognize compensation expense for these awards as summarized in the following table.

	Stock pensation
Years Ending December 31,	xpense
2020	\$ 1,627
2021	1,627
2022	1,493
2023	554
2024	148

14. INCOME TAXES

Details of the provision for income taxes consist of the following:

		Year Ended December 31.	
	2019	2018	
Research and development expense	\$(32,508)	\$ (9,006)	
Sales and marketing expense	(9,641)	(3,145)	
General and administrative expense	42,149	12,151	
	\$ -	\$ -	
Current	\$ -	\$ -	
Deferred	(42,149)	(12,151)	
Valuation allowance`	42,149	12,151	
Total	\$ -	\$ -	

The reasons for the difference between the statutory federal income tax rate and the Company's effective income tax rate as of December 31, 2019 and 2018, are as follows:

	Year Ended	
_	December 31,	
	2019	2018
Federal income tax rate	21.0%	21.0%
State taxes	6.3	7.9
Other	0.4	1.5
Valuation allowance	(27.7)	(30.4)
Total	-%	-%

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2019 and 2018, are as follows:

	As of December 31,			
	201	2019		18
	Assets	Liabilities	Assets	Liabilities
Acquired in-process research and development	\$ 50,628	\$ -	\$ 39,581	\$ -
Net operating loss carryforward	41,427	-	16,619	-
Accrued compensation	5,158	-	1,432	-
Credits	1,682	-	837	-
Disallowed interest	1,661	-	-	-
Deferred rent	160	-	95	-
Fixed assets	46	-	-	85
Other	61	167	57	29
Total	\$ 100,823	167	58,621	114
Net deferred tax asset	\$ 100,656	\$ -	58,507	\$ -
Valuation allowance	\$(100,656)	\$ -	(58,507)	\$ -
Total	\$ -	\$ -	\$ -	\$ -

The Company has considered available positive and negative evidence to estimate if sufficient future taxable income will be generated to allow utilization of the existing deferred tax assets. The

Company has incurred operating losses and negative cash flows from operations since inception. In light of these considerations, as well as the uncertainty as to when the Company might generate taxable income, the Company has recorded a full valuation allowance of \$100,656, which represents an increase of \$42,149 in the Company's valuation allowance from December 31, 2018 to December 31, 2019. The amount of the net deferred tax asset considered realizable could be adjusted in the future if estimates of taxable income change or if objective negative evidence in no longer present and additional weight may be given to subjective evidence.

As of December 31, 2019, the Company has approximately \$147,823 of federal net operating loss ("NOL") carryforward available to offset future federal taxable income. The Company also has approximately \$139,336 of state NOL carryforwards as of December 31, 2019 available to offset future state taxable income. All of the Company's tax years remain open to examination by federal and state taxing authorities. The Company's pre-2018 federal NOLs expire in 2037 whereas the Company's NOLs arising in 2018, and subsequent years, have an unlimited carryforward period. The Company's state NOLs begin to expire in 2037. Utilization of the net operating loss carryforwards may be subject to a substantial limitation due to ownership change limitations that may occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

As of December 31, 2019, the Company has approximately \$6,072 of excess interest expense carryforwards available to offset future federal and state taxable income. The excess interest carryforward has an unlimited carryforward term.

15. NET LOSS PER SHARE

The Company used the two-class method to compute net income (loss) per common share because the Company has issued securities (convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by the amount of any dividends earned and the accretion of convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of convertible preferred stock to the extent that each preferred security may share in the earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

Diluted net income (loss) per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, warrants, and convertible debt. In addition, the Company analyzes the potential dilutive effects of the outstanding convertible preferred stock under the 'if-converted' method when calculating diluted earnings per share, in which it is assumed that the outstanding convertible preferred stock converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (two-class or 'if converted') as their diluted net income per share during the period.

The Company has reported a net loss for the years ended December 31, 2019 and 2018, and the basic and diluted net loss per share attributable to common stockholders are the same for each year

because all convertible preferred stock and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact.

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,		er 31,	
		2019		2018
Numerator				
Net Loss	\$	(151,977)	\$	(39,898)
Accumulation of yield on preferred stock		(35,231)		(30,185)
Net loss available to common shareholders	\$	(187,208)	\$	(70,083)
Denominator				
Weighted-average common share outstanding basic and diluted	6	3,891,677	7:	2,765,366
Net loss per share attributed to common stockholders, basic and diluted	\$	(2.93)	\$	(0.96)

Potential common shares issuable upon conversion of preferred stock and exercise of stock options that are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	Year Ended D	ecember 31,
	2019	2018
Stock options to purchase common stock	18,661,458	13,825,301
Convertible preferred stock	303,064,300	292,495,890
Total	321,725,758	306,321,191

16. RELATED-PARTY TRANSACTIONS

The Company is party to a management agreement for professional services provided by a related party. The related party is an entity that shares common ownership with the Company. In addition, a member of the Company's board of directors is the president and owner of the entity. For the years ended December 31, 2019 and 2018, the Company incurred \$5,378 and \$4,276, respectively, in management fee expense and other expenses to this related party, which are included in general and administrative expense in the consolidated statement of operations and comprehensive loss. In addition, the Company participates in certain transactions with separate related parties that also share common ownership with the Company, primarily related to combined employee health plans. As of December 31, 2019, and 2018, the amount due to related parties included in current liabilities is \$1,208 and \$182, respectively, and the amount included in other assets is \$210 and \$42, respectively.

17. SUBSEQUENT EVENTS

On January 9, 2020 the Company entered into a credit agreement with OrbiMed Royalty & Credit Opportunities, LP for an aggregate amount of \$200,000 (the "New Loan"), which matures in January 2026. The New Loan bears an interest rate equal to the sum of (i) the greater of (a) 1-month LIBOR or (b) 2.00% per annum, plus (ii) 11.00% per annum, paid in cash monthly in arrears on the last day of each month starting in January 2020. In addition to entering into the New Loan, the Company extinguished the previous Loan with CRG Servicing LLC which required a payoff amount of \$120,893 consisting of principal repayment, interest, and exit fees. Net cash received as a result of the transaction, less debt issuance costs of \$5,778, was \$73,313. As of December 31, 2019, there was \$789 of debt issuance costs incurred and recorded as a noncurrent asset, of which \$689 were paid out of the January 2020 proceeds. These costs will be amortized as additional interest expense over the six-year loan term.

The recent outbreak in China of the Coronavirus Disease 2019, or COVID-19, which has been declared a global pandemic by the World Health Organization, has spread across the globe and is impacting worldwide economic activity. A public health epidemic, including COVID-19, poses the risk that we or our employees, contractors, suppliers, distributors and other partners, as well as physicians treating narcolepsy patients, may be prevented from conducting business and patient-care activities for an indefinite period of time, including due to shutdowns and quarantines that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected, particularly the United States and France, could disrupt the supply chain and the manufacture or shipment of WAKIX® and of drug substance and finished drug product for our clinical trials; impair our ability to meet demand for new WAKIX® prescriptions; impede our clinical trial recruitment, testing, monitoring, data collection and analysis and other related activities; and have a material impact our business, financial condition or results of operations. The company sole sources certain key components of its inventory, including the active pharmaceutical ingredient for WAKIX®, from France. The COVID-19 outbreak and mitigation measures may also have an adverse impact on global economic conditions, which could have a material effect on our business and financial condition. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands except per share data)

	March 31, 2020 (unaudited)	Dec	ember 31, 2019
ASSETS	(
CURRENT ASSETS:			
Cash and cash equivalents	\$ 71,517	\$	24,457
Trade receivables, net	11,308		4,255
Inventory, net	1,871		1,088
Prepaid expenses	5,638		1,436
Other current assets	168		261
Total current assets	90,502		31,497
NONCURRENT ASSETS:			
Property and equipment, net	1.233		1.330
Restricted cash	750		750
Intangible asset, net	70,400		72,185
Other noncurrent assets	209		941
Total noncurrent assets	72,592		75,206
TOTAL ASSETS	\$ 163,094	\$	106,703
	Ψ 105,094	Ψ	100,703
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT			
CURRENT LIABILITIES:			
Trade payables	\$ 4,851	\$	6,360
Accrued compensation	3,053		7,917
Accrued expenses	8,550		5,500
Other current liabilities			115
Total current liabilities	16,454		19,892
NONCURRENT LIABILITIES:			
Deferred rent	338		287
Warrant liability	3,505		-
Long term debt, net	192,177		97,946
Other noncurrent liabilities	307		163
Total noncurrent liabilities	196,327		98,396
TOTAL LIABILITIES	212,781		118,288
COMMITMENTS AND CONTINGENCIES (Note 9)			-,
CONVERTIBLE PREFERRED STOCK			
Convertible preferred stock, net of placement costs			
Series A convertible preferred stock—\$1.00 stated value; 286,000 shares authorized; 285,000 issued			
and outstanding at March 31, 2020 and December 31, 2019	357.822		348,203
Series B convertible preferred stock—\$1.25 stated value; 8,030 shares authorized; 8,000 issued and	001,022		0.0,200
outstanding at March 31, 2020 and December 31, 2019	12,331		12,023
Series C convertible preferred stock—\$1.96 stated value; 25,600 shares authorized; 25,510 issued	,		,0_0
and outstanding at March 31,2020 and December 31, 2019	52,490		51,051
STOCKHOLDERS' DEFICIT:	. ,		- ,
Common stock—\$0.00001 par value; 423,630 shares authorized; 64,125 and 63,974 issued and			
outstanding at March 31, 2020 and December 31, 2019, respectively	1		1
Accumulated deficit	(472,331)		(422,863)
TOTAL STOCKHOLDERS' DEFICIT	(472,330)		(422,862)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT	\$ 163,094	\$	106.703
TO THE EINDIETTIES, CONVERTIBLE FIXED EINIED STOCK, AND STOCKHOLDERS DEFICIT	Ψ 103,034	φ	100,703

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands except per share data)

	Three Months Ended March 31,	
	2020	2019
Net product revenues	\$ 19,840	\$ -
Cost of product sold	3,474	<u>-</u>
Gross profit	16,366	-
Operating expenses:		
Research and development	3,431	52,990
Sales and marketing	13,254	6,191
General and administrative	9,290	3,962
Total operating expenses	25,975	63,143
Operating loss	(9,609)	(63,143)
Loss on debt extinguishment	(22,639)	-
Interest (expense) income, net	(6,372)	122
Loss before income taxes	(38,620)	(63,021)
Income taxes	-	-
Net loss and comprehensive loss	\$(38,620)	\$(63,021)
Accumulation of yield on preferred stock	(10,445)	(8,314)
Net loss available to common stockholders	\$(49,065)	\$(71,335)
LOSS PER SHARE:		
Loss per share, basic and diluted	\$ (0.77)	\$ (1.12)
Weighted average number of shares of common stock, basic and diluted	64,000	63,889

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (In thousands)

	St	le Preferred ock A, B, & C	Commo	on Stock	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares (1)	Amount	capital	deficit	deficit
Balance as of December 31, 2019	318,510	\$411,275	63,974	\$ 1	\$ -	\$ (422,863)	\$ (422,862)
Net loss	-	-	-	-	-	(38,620)	(38,620)
Preferred stock dividend, Series A	-	8,844	-	-	(519)	(8,325)	(8,844)
Preferred stock accretion, Series A	-	776	-	-	-	(776)	(776)
Preferred stock dividend, Series B	-	302	-	-	-	(302)	(302)
Preferred stock accretion, Series B	-	6	-	-	-	(6)	(6)
Preferred stock dividend, Series C	-	1,299	-	-	-	(1,299)	(1,299)
Preferred stock accretion, Series C	-	140	-	-	-	(140)	(140)
Exercise of Options	-	-	151	-	151	-	151
Stock-based compensation		<u> </u>			368		368
Balance as of March 31, 2020	318,510	\$422,642	64,125	\$ 1	\$ -	\$ (472,331)	\$ (472,330)
	St Serie:	le Preferred cock s A & B		on Stock	Additional paid-in	Accumulated	Total stockholders'
Delenge of December 21, 2010	Shares	Amount	Shares (1)	Amount	capital	deficit	deficit
Balance as of December 31, 2018	293,000	\$324,201	63,888	\$ 1	\$ -	\$ (242,674)	\$ (242,673)
Net loss	-	-	-	-	(000)	(63,021)	(63,021)
Preferred stock dividend, Series A	-	8,040	-	-	(326)	(7,713)	(8,039)
Preferred stock accretion. Series A	-	686	-	-	-	(686)	(686)

Preferred stock dividend, Series B

Preferred stock accretion, Series B

Stock-based compensation Balance as of March 31, 2019

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements

\$333,207

293,000

274

6

63,888

(274)

\$ (314,374)

(6)

(6)

\$ (314,373)

⁽¹⁾ Common stock of Harmony Bioscience Holdings, Inc.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands)

	Three Mont March	
CACLLELOWIC EDOM OPERATING ACTIVITIES	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES Net loss	\$ (38,620)	ተ /62 021\
Adjustments to reconcile net loss to net cash used in operating activities:	\$ (30,020)	\$(63,021)
Depreciation	97	89
Intangible amortization	1,786	09
Milestones associated with acquired in-process research & development (IPR&D)	1,700	50,000
Stock-based compensation expense	368	326
Stock appreciation rights market adjustment	107	520
Warrant expense	1.146	_
Noncash paid-in-kind interest expense	-	91
Debt issuance costs amortization	340	-
Loss on debt extinguishment	22,639	_
Change in operating assets and liabilities:	,000	
Trade receivables	(7,053)	-
Inventory	(783)	-
Prepaid expenses and other assets	(4,111)	1,209
Other non-current assets	732	313
Trade payables	(1,509)	1,810
Accrued expenses and other current liabilities	(1,929)	(1,498)
Other non-current liabilities	` 88	86
Net cash used in operating activities	(26,702)	(10,595)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(32)
Milestone associated with acquired in-process research & development (IPR&D)	-	(50,000)
Net cash used in investing activities		(50,032)
CASH FLOWS FROM FINANCING ACTIVITIES:		(00,002)
Proceeds from long term debt	200,000	20,000
Debt issuance costs	(5,804)	(1,784)
Extinguishment of debt	(102,538)	(1,101)
Extinguishment of debt exit fees	(18,047)	-
Proceeds from exercised options	151	-
Net cash provided by financing activities	73,762	18,216
NET INCREASE/(DECREASE) IN CASH	47.060	(42,411)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	25,207	84,023
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	<u>\$ 72,267</u>	\$ 41,612
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	\$ 6,214	\$ 108
Cash paid during the year for milestones	-	50,000
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Series A Preferred Stock accrued return	8,844	8,040
Series A accretion of issuance costs	776	686
Series B Preferred Stock accrued return	302	274
Series B accretion of issuance costs	6	6
Series C Preferred Stock accrued return	1,299	-
Series C accretion of issuance costs	140	-

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Our operating subsidiary, Harmony Biosciences, LLC, was formed on May 17, 2017. Harmony Biosciences Holdings, Inc. (the "Company") was founded on July 25, 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and the Company converted to a Delaware corporation named Harmony Biosciences II, Inc. on September 19, 2017. On February 3, 2020, the Company changed its name to Harmony Biosciences Holdings, Inc. The Company is a holding company and has no operations. The Company's operations are conducted in its wholly owned subsidiary, Harmony Biosciences, LLC ("Harmony"). Harmony is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients with rare neurological disorders living with unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

2. GOING CONCERN

The condensed consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred operating losses and negative cash flows from operations since inception. As of March 31, 2020, and December 31, 2019, the Company has an accumulated deficit of \$472,331 and \$422,863, respectively. Management anticipates to continue to incur operating losses and negative cash flows. In addition, as more fully described in Note 6, the Company is subject to potential milestone payments of up to \$142,000 associated with the License and Commercialization Agreement (the "License Agreement") with Bioprojet Société Civile de Recherche ("Bioprojet"). The Company has financed its operations to date with proceeds from the sale of preferred securities and debt financing.

The Company may need to raise additional capital in order to continue to fund operations, including milestone obligations under its licensing agreement. The Company believes that it will be able to obtain additional capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

Accordingly, these factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated balance sheet as of March 31, 2020, condensed consolidated statements of operations and comprehensive loss, condensed consolidated statements of cash flows, and the condensed consolidated statements of convertible preferred stock and shareholders' deficit for the

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

three months ended March 31, 2019 and 2020, are unaudited. The balance sheet as of December 31, 2019 was derived from audited financial statements as of and for the year ended December 31, 2019. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2019, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2020, and the results of its operations and its cash flows for the three months ended March 31, 2019 and 2020.

Fair Value of Financial Instruments

The Company's consolidated financial statements include cash, cash equivalents, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value. Additionally, the Company's consolidated financial statements include a warrant liability that is carried at fair value and is re-measured at each balance sheet date until it is exercised or expires and adjusted to fair value.

It is the Company's policy, in general, to measure non-financial assets and liabilities at fair value on a nonrecurring basis. The instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (such as evidence of impairment), which, if material, are disclosed in the accompanying footnotes.

The Company measures certain assets and liabilities at fair value in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy that serves to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1—Valuations based on unadjusted guoted prices in active markets for identical assets or liabilities.
- Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3—Valuations based on unobservable inputs and models that are supported by little or no market activity.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash and, if applicable, highly liquid investments with an original maturity of three months or less when purchased, including investments in Money Market Funds. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	As of		
	March 31, 2020	Dec	ember 31, 2019
Cash and cash equivalents	\$71,517	\$	24,457
Restricted cash	750		750
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$72,267	\$	25,207

Amounts included in restricted cash represent those amounts required to be held as a security deposit in the form of letters of credit for the Company's credit card program.

Concentrations of Risk

Substantially all of the Company's cash and money market funds are held with a single financial institution. Due to its size, the Company believes this financial institution represents minimal credit risk. Deposits in this institution may exceed the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation for U.S. institutions. The Company has not experienced any losses on its deposits of cash and cash equivalents. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

We are also subject to credit risk from our trade receivables related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to specialty pharmaceutical distribution companies within the U.S. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced credit losses on our accounts receivable. As of March 31, 2020, three customers accounted for 100% of gross accounts receivable, Caremark LLC ("CVS Caremark"), which accounted for 41% of gross accounts receivable; Accredo Health Group, Inc ("Accredo), which accounted for 31% of gross accounts receivable; and PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 28% of gross accounts receivable. For the three months ended March 31, 2020, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 42% of gross product revenues; Pantherx accounted for 35% of gross product revenues; and Accredo accounted for 23% of gross product revenues.

As of December 31, 2019, two customers accounted for 91% of gross accounts receivable; CVS Caremark, which accounted for 72% of gross accounts receivable, and Pantherx, which accounted for 19% of gross accounts receivable.

We depend on a single source supplier for our product, product candidates and their active pharmaceutical ingredient.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Cost of Product Sold

Cost of product sold include manufacturing and distribution costs, the cost of drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, and salaries of employees involved with production. The Company began capitalizing inventory upon FDA approval of WAKIX® with a portion of the inventory sold during the three months ended March 31, 2020 produced prior to FDA approval and, therefore, was previously expensed as research and development expense in 2019 in the amount of \$1,323. Excluded from cost of product sold shown on the consolidated statements of operations and comprehensive loss is amortization of acquired developed technology of \$1,786 and \$0 in the three months ended March 31, 2020 and March 31, 2019, respectively.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expense was \$2,454 in the three months ended March 31, 2020 and de minimis for the three months ended March 31, 2019.

Subsequent Events

The Company has evaluated and, as necessary, made changes to these consolidated financial statements for subsequent events through June 11, 2020, the date these consolidated financial statements were available to be issued. All subsequent events that provided additional evidence about conditions existing at the date of the consolidated statements of financial position were incorporated into the consolidated financial statements (see Note 16 for further detail).

4. INVENTORY

Inventory, net consisted of the following:

		As of
	March 31, 2020	December 31, 2019
Raw materials	\$ 1,001	\$ 384
Work in process	655	417
Finished goods	215	287
Total inventory, net	\$ 1,871	\$ 1,088

5. INTANGIBLE ASSET

On August 15, 2019, the Company received FDA approval of WAKIX® (pitolisant) for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. This event triggered a milestone payment of \$75,000 associated with the License Agreement which the Company capitalized as an intangible asset. The Company determined a useful life of 10 years for such intangible asset, and, as of March 31, 2020 the remaining useful life was 9.50 years. The Company expects the annual amortization to be \$7,407 for the next five years. Prior to this event, all other milestones associated with the License Agreement were expensed through research and development as they did not meet the criteria to recognize as an intangible asset.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

The gross carrying amount and net book value of the intangible asset is as follows:

	A	As of		
	March 31, 2020	Dec	ember 31, 2019	
Gross Carrying Amount	\$75,000	\$	75,000	
Accumulated Amortization	(4,600)		(2,815)	
Net Book Value	\$70,400	\$	72,185	

6. LICENSE AGREEMENT

On July 28, 2017, Harmony entered into the License Agreement whereby Harmony acquired the exclusive right to commercialize the pharmaceutical compound pitolisant for the treatment, and/or prevention, of narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, and Parkinson's disease as well as any other indications unanimously agreed by the parties in the United States and its territories. A milestone of \$50,000 was due upon acceptance by the FDA of pitolisant's New Drug Application ("NDA"), which was achieved on February 12, 2019 and was expensed within research and development for the year ended December 31, 2019. In addition, a milestone of \$77,000, including a \$2,000 fee, was due upon FDA approval of WAKIX® (pitolisant) for treatment of EDS in adult patients with narcolepsy, which was achieved on August 15, 2019. The License Agreement also requires sales-based milestones, a fixed trademark royalty and a tiered royalty, all based on net sales, which becomes due and payable to Bioprojet on a quarterly basis with an additional milestone of \$102,000 due upon FDA approval of other specific indications and \$40,000 due upon reaching specific sales milestone. During the three months ended March 31, 2020 and 2019, the Company has incurred \$3,227 and \$0, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of March 31, 2020 and December 31, 2019, the Company had accrued \$3,227 and \$938, respectively, for sales-based, trademark and tiered royalties.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	I	As of
	March 31, 2020	December 31, 2019
Royalties due to third parties	\$ 3,227	\$ 938
Rebates and other sales deductions	1,731	713
Research and development	1,406	894
Selling and marketing	1,059	1,547
Professional fees, consulting, and other services	943	510
Debt issuance costs	_	638
Employee travel and other expenses	<u> 184</u>	260
	<u>\$ 8,550</u>	\$ 5,500

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

8. DEBT

Credit Agreements

On February 28, 2019, the Company entered into a multi-draw loan agreement with CRG Servicing LLC for an aggregate of \$200,000 (the "CRG Loan"), which matured in March 2025. The Loan bore a fixed rate of 12%. The Loan agreement required compliance with certain financial covenants. The Company could draw three tranches of the Loan based on achieving specific milestones and dates. The Company could elect to pay the interest on the outstanding principal amount as follows: (i) only 7.5% of the 12% per annum in cash, paid quarterly, starting in March 2019, and (ii) 4.5% of the 12% per annum interest as compounded interest, added to the aggregate outstanding principal balance quarterly; the amount of any such compounded interest being a paid-in-kind loan.

As of December 31, 2019, the Company had borrowed \$100,000, resulting in cash proceeds received of \$94,816, net of issuance costs. The issuance costs of \$5,184 were being amortized over the six-year loan term of the CRG Loan. Unamortized debt issuance costs as of December 31, 2019 are \$4,592 and are presented in the consolidated balance sheets as a direct deduction from the carrying value of the debt.

On January 9, 2020 the Company entered into a credit agreement with OrbiMed Royalty & Credit Opportunities, LP for an aggregate amount of \$200,000 (the "OrbiMed Loan"), which matures in January 2026. The OrbiMed Loan bears an interest rate equal to the sum of (i) the greater of (a) 1-month LIBOR or (b) 2.00% per annum, plus (ii) 11.00% per annum, paid in cash monthly in arrears on the last day of each month starting in January 2020. In addition to entering into the OrbiMed Loan, the Company extinguished the CRG Loan which required a payoff amount of \$120,893 consisting of principal repayment, interest, and exit fees. In connection with extinguishment of the CRG Loan, we recognized a loss on extinguishment of \$22,639, which included an exit fee of \$18,047 and the write-off of the remaining unamortized debt issuance costs of \$4,592. The loss on extinguishment of debt was recorded in loss on debt extinguishment within our consolidated statement of operations. The net cash received as a result of the transaction, less debt issuance costs of \$5,778, was \$73,313. These debt issuance costs will be amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. Unamortized debt issuance costs as of March 31, 2020 are \$5,562 and are presented in the consolidated balance sheets as a direct deduction from the carrying value of the debt.

In connection with the OrbiMed Loan, the Company issued a warrant (the "Warrant") to OrbiMed Royalty & Credit Opportunities, LP on January 9, 2020. Pursuant to the Warrant, OrbiMed Royalty & Credit Opportunities, LP, may purchase up to 3,370 shares of the Company's Series C Preferred Stock for an initial exercise price of \$1.96 at any time from the date of execution of the Warrant through the expiration date, defined within the Warrant as the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization. The exercise price is subject to adjustments, among other things, for stock splits and stock dividends. The fair value of the Warrant using the Black-Scholes option-pricing model was \$2,359 at January 9, 2020 and \$3,505 at March 31, 2020. See footnote 14 for the fair value of the Warrants. This amount was recorded as a warrant liability which is included in warrant liability in the consolidated balance sheet at March 31, 2020. The portion of the OrbiMed Loan proceeds allocated to the warrant liability resulted in a debt discount, which is presented in the consolidated balance sheets as a direct deduction from the carrying value of the debt and is being amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. The unamortized debt discount as of March 31, 2020 is \$2,261 and is presented in the consolidated balance sheets as a

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

direct deduction from the carrying value of the debt. During the three months ended March 31, 2020, a loss of \$1,146 was recorded in general and administrative expenses in the consolidated statement of operations due to the change in the fair value of the warrant liability.

Interest paid for all outstanding debt totaled \$6,214 and \$108 during the three months ended March 31, 2020 and 2019, respectively.

9. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company is subject to claims and suits arising in the ordinary course of business. The Company accrues for such liabilities when they are known if they are deemed probable and can be reasonably estimated.

During 2018 and 2019 the Company had an ongoing litigation with the former chief executive officer related to the value and arbitration of vested common shares. On October 24, 2019 the Company reached a settlement resulting in \$3,466 of general and administrative expense reflected in the Company's consolidated results of operations for the year ended December 31, 2019.

Lease Agreements

In April 2018, the Company entered into an operating lease for approximately nine thousand square feet of office space in Northbrook, IL, which expired in January 2020.

In June 2018, the Company entered into an operating lease for approximately seven thousand square feet of office space in Plymouth Meeting, PA, which expires in May 2024.

In November 2019, the Company entered into an operating lease for approximately four thousand square feet of office space in Chicago, IL, which expires in December 2020.

The terms of the lease payments provide for rental payments on a monthly basis and on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. In addition, tenant improvement allowances recorded are amortized as a reduction to rent expense on a straight-line basis over the lease term. Rent expense was \$204 and \$141 for the three months ended March 31, 2020 and 2019, respectively. The following table sets forth the lease payment obligations as of March 31, 2020, for the periods indicated below:

Years ending December 31,	
2020	\$ 545
2021	443
2022	443
2023	443
2024	148
Thereafter	-
Total	\$2,022

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

10. CONVERTIBLE PREFERRED STOCK

Series A Preferred Stock

On September 22, 2017, the Company issued 270,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$270,000 in the aggregate. On January 8, 2018, the Company issued an additional 15,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$15,000 in the aggregate. As of March 31, 2020, and December 31, 2019, there were 286,000 Series A convertible preferred stock authorized of which 285,000 were issued and outstanding. Each outstanding share of Series A convertible preferred stock accrues dividends at 10% per annum of the Series A original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series A convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return is calculated on the original issue price and was \$77,608 and \$68,764 at March 31, 2020 and December 31, 2019, respectively. For the three months ended March 31, 2020, and 2019, accretion of issuance costs of \$776 and \$686, respectively, was recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$4,786 and \$7,619, respectively, are recorded as a direct reduction of Series A convertible preferred stock in the Company's consolidated balance sheet.

Series B Preferred Stock

On January 8, 2018, the Company issued 8,000 shares of Series B convertible preferred stock for a purchase price of \$1.25 per share, or \$10,000 in the aggregate. As of March 31, 2020 and December 31, 2019, there were 8,030 shares of Series B convertible preferred stock authorized, of which 8,000 were issued and outstanding. Each outstanding share of Series B convertible preferred stock accrues dividends at 10% per annum of the Series B original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series B convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return is calculated on original issue price and was \$2,378 and \$2,076 at March 31, 2020 and December 31, 2019, respectively. For the three months ended March 31, 2020 and 2019, accretion of issuance costs of \$6 and \$6, respectively, was recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$47 and \$70, respectively, are recorded as a direct reduction of Series B convertible preferred stock in the Company's consolidated balance sheet.

Series C Preferred Stock

On August 9, 2019, the Company issued 25,510 shares of Series C convertible preferred stock for a purchase price of \$1.96 per share, or \$50,000 in the aggregate. As of March 31, 2020 and December 31, 2019, there were 25,600 shares of Series C convertible preferred stock authorized, of which 25,510 were issued and outstanding. Each outstanding share of Series C convertible preferred stock accrues dividends at 10% per annum of the Series C original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series C convertible preferred stock are cumulative and are compounded annually. The cumulative unpaid preferred return is calculated on original issue price and was \$3,272 and \$1,973 at March 31, 2020 and December 31, 2019, respectively. For the three months ended March 31, 2020 and 2019, accretion of issuance costs of \$140 and \$0 were recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$781 and \$0, respectively, are

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

recorded as a direct reduction of Series C convertible preferred stock in the Company's consolidated balance sheet.

Redemption

The holders of a majority of the issued and outstanding Series A, Series B, and Series C convertible preferred stock may require that the Company redeem all of the issued and outstanding shares of Series A, Series B, and Series C convertible preferred stock at any time on or after September 22, 2021. The per share redemption price will be equal to the Series A original issue price for the Series A convertible preferred stock, the Series B original issue price for the Series B convertible preferred stock, and Series C original issue price for the convertible preferred stock, plus, in each case, the amount of accrued and unpaid preferred dividends with respect to such shares.

Optional Conversion Rights

Each share of Series A, Series B, and Series C convertible preferred stock is convertible, at any time at the option of the holder, into such number of fully paid shares of common stock as is determined by dividing (x) the applicable original issuance price by (y) the conversion price in effect at the time of conversion. Accordingly, each share of Series A, Series B, and Series C convertible preferred stock is convertible into common stock on a one-for-one basis. Each applicable conversion price is subject to adjustment for any stock dividends, stock splits or stock combinations, reclassifications or exchanges of similar stock, upon a reorganization, merger or consolidation of the Company, or upon the issuance or sale by the Company of common stock for consideration less than the applicable conversion price.

Mandatory Conversion Rights

Each share of Series A, Series B, and Series C convertible preferred stock will automatically convert into the number of shares of common stock determined in accordance with the conversion rate applicable to optional conversions, as described above, upon the closing of the sale of shares of the Company's common stock to the public at a price of at least \$3.92 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$100,000 of gross proceeds, net of underwriting discounts and commissions, to the Company.

Dividends

The holders of Series A, Series B, and Series C convertible preferred stock are entitled to receive, when and if declared by the board of directors of the Company, cumulative dividends equal to a 10% per annum of Series A, Series B, and Series C convertible preferred stock. In addition, the holders of the outstanding shares of Series A, Series B, and Series C convertible preferred stock are entitled to receive, when and if declared by the board of directors of the Company, a dividend at least equal to any dividend payable on the Company's common stock as if all convertible preferred stock had been converted to common stock. No dividends have been declared as of March 31, 2020 and December 31, 2019.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Liquidation

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Series A, Series B, and Series C convertible preferred stock shall be entitled to receive pro rata, prior and in preference to any distribution to the holders of the common stock, an amount equal to the greater of (i) the original issuance prices of each series (in each case, as adjusted for stock splits, stock dividends or distributions, recapitalizations, and similar events) and all accrued but unpaid dividends, if any or (ii) such amount per share as would have been payable had all shares of Series A, Series B, and Series C convertible preferred stock been converted to common stock. If the assets and funds to be distributed among the holders of convertible preferred stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Voting Rights

Each share of convertible preferred stock has a number of votes equal to the number of shares of common stock into which it is convertible. The holders of convertible preferred stock, voting together as a single class, shall be entitled to elect six members of the Company's board of directors. The holders of common stock have the right to elect two members of the Company's board of directors. With respect to any other matter presented to the stockholders for their consideration or action at any meeting of the board of directors, the holders of the Series A, Series B, and Series C convertible preferred stock are entitled to cast the number of votes equal to the number of whole shares of common stock into which such preferred shares are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of the Series A, Series B, and Series C convertible preferred stock are entitled to vote together with the holders of common stock as a single class. In addition, certain matters, prior to being able to be undertaken by the Company, require the approval of a majority of the holders of the Company's convertible preferred stock, voting as a separate class.

11. STOCKHOLDERS' DEFICIT

Common Stock

On September 19, 2017, Harmony Biosciences II, LLC, was converted to a C corporation named Harmony Biosciences II, Inc., at which point the 63,333 outstanding common units of Harmony Biosciences II, LLC, were converted to 63,333 common shares of Harmony Biosciences II, Inc.

On September 22, 2017, the Company issued warrants for 13,889 common shares, with an exercise price of \$0.01 per share, to the holders of the Convertible Notes upon the consummation of an equity financing transaction and these warrants were immediately exercised resulting in the issuance of 13,889 common shares and proceeds of \$139.

On August 31, 2018, the Company repurchased and canceled 13,333 common shares from the former chief executive officer for \$3,200.

As of March 31, 2020, and December 31, 2019 there were 423,630 common shares authorized, of which 64,125 and 63,974 were issued and outstanding, respectively. After the preferences of the preferred stock are paid, distributions are made to the holders of the common shares.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Holders of common shares are entitled to one vote for each share of common stock held. Holders of common shares have voting privileges with respect to the election of two of the eight directors of the board of directors of the Company, and any other matter presented to the shareholders for their consideration or action at any meeting of the board of directors. Holders of common shares may not vote on amendments to the Company's Certificate of Incorporation that relate solely to the terms of one or more outstanding Series of preferred stock if the holders of such affected Series are entitled, either separately or together with the holders of one or more other such Series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law.

10,000 common shares held by an investor were subject to certain forfeiture provisions that are dependent upon the outcome of certain future events. On November 15, 2019, the Company removed the provision associated with this forfeiture resulting in \$8,400 of noncash stock compensation expense reflected in the Company's consolidated results of operations for the year ended December 31, 2019.

12. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

Stock Incentive Plan

On August 7, 2017, the Company adopted an equity incentive plan (the "Plan"). Under the Plan, directors, officers, employees, consultants, and advisors of the Company can be paid incentive compensation measured by the value of the Company's common shares through grants of stock options, stock appreciation rights, or restricted stock.

Awards under the Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement (generally five years from the date of grant), at achievement of a performance requirement, or upon change of control (as defined in the applicable plan).

Changes in awards granted under the Plan as of March 31, 2020 and December 31, 2019, are as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Awards outstanding—December 31, 2019	19,513	\$ 1.00	8.33
Stock options issued	1,283	\$ 1.00	
Stock options exercised	(151)	\$ 1.00	
Stock options forfeited	(485)	\$ 1.00	
Awards outstanding—March 31, 2020	20,160	\$ 1.00	8.17

As of March 31, 2020 and December 31, 2019, stock awards issued under the Plan for 5,584 and 4,708 common shares, respectively, were vested. The Company has elected early adoption of ASU No. 2016-09 to recognize forfeitures as they occur. As a result of the adoption, for the three months ended March 31, 2020 and 2019, the Company reversed \$10 and \$4, respectively, of stock-based compensation previously recorded.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Value of Stock Options

The Company has valued awards for each of the plans included herein using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on historical volatility of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for the time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The assumptions used to value the awards are summarized in the following table.

	<i>_</i>	As of	
	March 31, 2020	December 31, 2019	
Dividend yield	0.00%	0.00%	
Expected volatility	95.80%	95.30 - 99.30%	
Risk-free interest rate	0.51%	1.60 - 2.59%	
Lack of marketability discount	20.48%	26.00 - 31.00%	
Expected term (years)	6.5	6.5	

The weighted average per share fair value of awards issued under the Plan was \$0.45 and \$0.42 for the three months ended March 31, 2020 and 2019, respectively.

Stock-based compensation expense was \$475 and \$326 for the three months ended March 31, 2020 and 2019, respectively, and was recorded in the consolidated statement of operations and comprehensive loss in the following line items:

	Three Months Ended March 31.		
	 020		2019
Research and development expense	\$ 80	\$	61
Sales and marketing expense	108		57
General and administrative expense	287		208
	\$ 475	\$	326

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

Awards issued under the Plan are reflected as a component of equity in these consolidated financial statements. The Company will recognize compensation expense for these awards as summarized in the following table.

Vicin Festiva Province of	Stock Compensation		
Years Ending December 31,		Expense	
2020	\$	1,789	
2021		1,816	
2022		1,684	
2023		779	
2024		321	
2025		28	

13. NET LOSS PER SHARE

The Company used the two-class method to compute net income (loss) per common share because the Company has issued securities (convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by the amount of any dividends earned and the accretion of convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of convertible preferred stock to the extent that each preferred security may share in the earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

Diluted net income (loss) per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, warrants, and convertible debt. In addition, the Company analyzes the potential dilutive effects of the outstanding convertible preferred stock under the 'if-converted' method when calculating diluted earnings per share, in which it is assumed that the outstanding convertible preferred stock converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (two-class or 'if converted') as their diluted net income per share during the period.

The Company has reported a net loss for the three months ended March 31, 2020 and 2019, and the basic and diluted net loss per share attributable to common stockholders are the same for each three month period because all convertible preferred stock and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

The following table sets forth the computation of basic and diluted net loss per share:

		Three Months Ended March 31,	
	2020	2019	
Numerator			
Net Loss	\$(38,620)	\$(63,021)	
Accumulation of yield on preferred stock	(10,445)	(8,314)	
Net loss available to common shareholders	\$(49,065)	\$(71,335)	
Denominator			
Weighted-average common share outstanding basic and diluted	64,000	63,889	
Net loss per share attributed to common stockholders, basic and diluted	\$ (0.77)	\$ (1.12)	

Potential common shares issuable upon conversion of preferred stock and exercise of stock options that are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	Three Months Ended March 31,	
	2020	2019
Stock options to purchase common stock	19,827	17,075
Convertible preferred stock	321,547	293,000
Total	341,374	310,075

14. FINANCIAL INSTRUMENTS

We primarily apply the market approach to determine the fair value of financial instruments that are measured at fair value on a recurring basis. There were no changes to our valuation techniques used to determine the fair value of financial instruments during the three months ended March 31, 2020. The Company's financial assets which are measured at fair value on a recurring basis were comprised of cash, cash equivalents, and restricted cash of \$72,267 and \$25,207 at March 31, 2020 and December 31, 2019, respectively, based on Level 1 inputs, and a warrant liability of \$3,505 and \$0 at March 31, 2020 and December 31, 2019, respectively, based on Level 3 inputs.

The Company estimates the fair value of the warrant liability using the Black-Scholes option-pricing model at each balance sheet date. This amount is recorded as warrant liability in the consolidated balance sheets at March 31, 2020. Any subsequent changes in the fair value of the warrant liability will be recorded in current period earnings as a general and administrative expense. During the three months ended March 31, 2020 and 2019, a loss of \$1,146 and \$0, respectively, was recorded in general and administrative expenses in the consolidated statement of operations due to the change in the fair value of the warrant liability.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (In thousands except per share data)

The assumptions used to determine the fair value of the warrant liability as of March 31, 2020 were as follows:

Dividend yield	0.00%
Expected volatility	54.2%
Risk-free interest rate	0.23%
Lack of marketability discount	0.00%
Dividend yield	0.00%
Expected term (years)	1.2

15. RELATED-PARTY TRANSACTIONS

The Company is party to a management agreement for professional services provided by a related party. The related party is an entity that shares common ownership with the Company. In addition, a member of the Company's board of directors is the president and owner of the entity. For the three months ended March 31, 2020 and 2019, the Company incurred \$1,730 and \$1,186, respectively, in management fee expense and other expenses to this related party, which are included in general and administrative expense in the consolidated statement of operations and comprehensive loss. In addition, the Company participates in certain transactions with separate related parties that also share common ownership with the Company, primarily related to combined employee health plans. As of March 31, 2020, and December 31, 2019, the amount due to related parties included in current liabilities was \$232 and \$1,208, respectively, and the amount included in other assets was \$1 and \$210, respectively.

16. SUBSEQUENT EVENTS

The recent outbreak in China of the Coronavirus Disease 2019 ("COVID-19"), which has been declared a global pandemic by the World Health Organization, has spread across the globe and is impacting worldwide economic activity. A public health epidemic, including COVID-19, poses the risk that we or our employees, contractors, suppliers, distributors and other partners, as well as physicians treating narcolepsy patients, may be prevented from conducting business and patient-care activities for an indefinite period of time, including due to shutdowns and quarantines that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected, particularly France and the United States, could disrupt the supply chain and the manufacture or shipment of WAKIX® and of drug substance and finished drug product for our clinical trials; impair our ability to meet demand for new WAKIX® prescriptions; impede our clinical trial recruitment, testing, monitoring, data collection and analysis and other related activities; and have a material impact on our business, financial condition or results of operations. The company sole sources certain key components of its inventory, including the active pharmaceutical ingredient for WAKIX®, from France and the United States. The COVID-19 outbreak and mitigation measures may also have an adverse impact on global economic conditions, which could have a material effect on our business and financial condition. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

The Company has evaluated subsequent events through June 11, 2020, which is the date the consolidated financial statements were available to be issued. Any material subsequent events that occurred during this time have been properly recognized or disclosed in the consolidated financial statements and accompanying notes.

Shares



Common Stock

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other expenses of issuance and distribution.

The following table sets forth all fees and expenses, other than the underwriting discounts and commissions payable solely by Harmony Biosciences Holdings, Inc. in connection with the offer and sale of the securities being registered. All amounts shown are estimated except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the exchange listing fee.

	unt to be paid
SEC registration fee	\$ *
FINRA filing fee	*
Exchange listing fee	*
Accounting fees and expenses	*
Legal fees and expenses	*
Printing expenses	*
Transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	\$ *

To be completed by amendment.

Item 14. Indemnification of directors and officers.

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides that no director of Harmony Biosciences Holdings, Inc. shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that

the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon consummation of this offering, our amended and restated certificate of incorporation and amended and restated bylaws will provide indemnification for our directors and officers to the fullest extent permitted by the General Corporation Law of the State of Delaware. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement will provide, among other things, for indemnification to the fullest extent permitted by law and our amended and restated certificate of incorporation and amended and restated bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements will provide for the advancement or payment of all expenses to the indemnitee and for the reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our amended and restated certificate of incorporation and amended and restated bylaws.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended (the "Securities Act") against certain liabilities.

Item 15. Recent sales of unregistered securities.

During the past three years, we issued securities that were not registered under the Securities Act as set forth below. The following is a summary of transactions during the preceding three fiscal years involving sales of our securities that were not registered under the Securities Act:

(a) Issuance of Capital Stock

From September 22, 2017 through January 8, 2018, we issued and sold an aggregate of 285,000,000 shares of our Series A convertible preferred stock, or Series A stock, at a purchase price of \$1.00 per share for aggregate consideration of approximately \$285,000,000.

On January 8, 2018, we issued and sold an aggregate of 8,000,000 shares of our Series B convertible preferred stock, or Series B stock, at a purchase price of \$1.25 per share for aggregate consideration of approximately \$10,000,000.

On August 9, 2019, we issued and sold an aggregate of 25,510,205 shares of our Series C convertible preferred stock at a purchase price of \$1.96 per share, for aggregate consideration of approximately \$50,000,000.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipients of securities in the transactions described above represented that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions.

(b) Stock Option Grants and Option Exercises

From September 16, 2017 through March 31, 2020, we granted to our employees, directors, consultants and certain employees and affiliates of Paragon options to purchase up to 21,663,768 shares of common stock under our Equity Incentive Plan, at an exercise price of \$1.00 per share. 1,597,282 of these options were terminated, expired without being exercised or were otherwise forfeited.

As of March 31, 2020, we have issued an aggregate of 236,182 shares of common stock pursuant to the exercise of stock options by employees and affiliates of Paragon. These issuances were exempt from the registration requirements of the Securities Act pursuant to Section 4(w) of the Securities Act, Rule 701 and/or Regulation S.

From September 16, 2017 through March 31, 2020, we granted stock appreciation rights to certain employees and affiliates of Paragon for up to 380,000 shares of common stock under our Equity Incentive Plan, at an exercise price of \$1.00 per share. Of the stock appreciation rights granted through March 31, 2020, stock appreciation rights for 50,000 shares of common stock were terminated, expired without being exercised or were otherwise forfeited.

No underwriters were involved in the foregoing issuances of securities. The issuances of stock options described in this paragraph (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors, consultants and advisors, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the

Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

(c) Issuance of Warrants

On January 9, 2020, we issued warrants exercisable for up to 3,370,122 shares of our Series C convertible preferred stock at a price of \$1.96 per share.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and financial statements.

Exhibit No.	
1.1*	Form of Underwriting Agreement.
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant, as in effect prior to the consummation of this offering.
3.2	Amendment to Third Amended and Restated Certificate of Incorporation of the Registrant, as in effect prior to the consummation of this offering.
3.3	Second Amendment to Third Amended and Restated Certificate of Incorporation of the Registrant, in effect prior to the consummation of this offering.
3.4*	Third Amendment to Third Amended and Restated Certificate of Incorporation of the Registrant, in effect prior to the consummation of this offering.
3.5*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the consummation of this offering.
3.6*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the consummation of this offering.
4.1*	Specimen Stock Certificate evidencing the shares of common stock.
5.1*	Opinion of Latham & Watkins LLP.
10.1#	Credit Agreement, dated as of January 9, 2020, among Harmony Biosciences, LLC, the Lenders from time to time party thereto and OrbiMed Royalty & Credit Opportunities III, LP.
10.2	<u>Pledge and Security Agreement, dated as of January 9, 2020, among Harmony Biosciences, LLC, the Registrant, OrbiMed Royalty & Credit Opportunities III, LP and the Secured Parties as defined therein.</u>
10.3*†	Harmony Biosciences II, Inc. Equity Incentive Plan and form of agreement.

Exhibit No.	
10.4*†	2020 Incentive Award Plan and form of agreement.
10.5*†	Employment Agreement, dated September 6, 2017, by and between Harmony Biosciences, LLC and John C. Jacobs.
10.6*†	Offer Letter, dated October 10, 2017, by and between Harmony Biosciences, LLC and Jeffrey Dayno.
10.7*†	Offer Letter, dated September 8, 2017, by and between Harmony Biosciences, LLC and Andrew Serafin.
10.8*†	Offer Letter, dated September 29, 2018, by and between Harmony Biosciences, LLC and John Vittoria.
10.9*	Form of Indemnification Agreement between Harmony Biosciences, LLC and each director and executive officer.
10.10#	<u>License and Commercialization Agreement, dated July 28, 2017, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.</u>
10.11	Amendment No. 1 to License and Commercialization Agreement, dated August 27, 2018, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.
10.12#	Trademark License Agreement, dated August 23, 2018, by and among Bioprojet Europe, Ltd., Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.
10.13	<u>Management Services Agreement, dated September 22, 2017, by and between Paragon Biosciences, LLC and Harmony Biosciences, LLC.</u>
10.14	Right of Use Agreement, dated November 1, 2019, by and between Paragon Biosciences, LLC and Harmony Biosciences, LLC.
10.15	Second Amended and Restated Investors' Rights Agreement, dated August 9, 2019, by and among the Registrant and the other parties thereto.
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).

^{*} To be filed by amendment.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

[†] Indicates a management contract or compensatory plan or arrangement.

[#] Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

- (b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
 - (c) The undersigned hereby further undertakes that:
- (1) For purposes of determining any liability under the Securities Act the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Plymouth Meeting, State of Pennsylvania, on . 2020.

By:					
Name:	John C. Jacobs				

Title: Chief Executive Officer and Director

HARMONY BIOSCIENCES HOLDINGS, INC.

POWER OF ATTORNEY

Each of the undersigned officers and directors of Harmony Biosciences Holdings, Inc. hereby constitutes and appoints John C. Jacobs and Susan L. Drexler, and each of them any of whom may act without joinder of the other, the individual's true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for the person and in his or her name, place and stead, in any and all capacities, to sign this registration statement on Form S-1, and any other registration statement relating to the same offering (including any registration statement, or amendment thereto, that is to become effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended), and any and all amendments thereto (including post-effective amendments to the registration statement), and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities set forth opposite their names and on the date indicated above.

<u>Signature</u>	<u>Title</u>	Date
John C. Jacobs	Chief Executive Officer and Director (Principal Executive Officer)	, 2020
Susan L. Drexler	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2020
Jeffrey S. Aronin	Chairman of the Board	, 2020
Martin Edwards	Director	, 2020
Antonio Gracias	Director	, 2020

<u>Signature</u>		<u>Title</u>	Date
Jack Bech Nielsen	Director		, 2020
Aaron Royston	Director		, 2020
Juan A. Sabater	Director		, 2020
Dr. Andreas Wicki	Director		, 2020

THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF HARMONY BIOSCIENCES II, INC.

(Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware)

Harmony Biosciences II, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

- **1.** That the name of this corporation is Harmony Biosciences II, Inc., and that this corporation was originally organized as a limited liability company pursuant to the Delaware Limited Liability Company Act on July 25, 2017 under the name Harmony Biosciences II, LLC.
- **2.** That pursuant to that certain Certificate of Conversion, dated as of September 19, 2017, that certain Certificate of Incorporation, dated as of September 19, 2017 (the "Certificate of Incorporation") and Section 265 of the General Corporation Law, Harmony Biosciences II, LLC was duly converted into a corporation, formed and existing under the General Corporation Law as of September 19, 2017.
- 3. That the Certificate of Incorporation was amended and restated by that certain Amended and Restated Certificate of Incorporation of this corporation that was filed with the Secretary of State of the State of Delaware pursuant to the General Corporation Law on September 21, 2017 (the "A&R Certificate of Incorporation").
- **4.** That the A&R Certificate of Incorporation was amended and restated by that certain Second Amended and Restated Certificate of Incorporation of this corporation that was filed with the Secretary of State of the State of Delaware pursuant to the General Corporation Law on January 5, 2018 (the "Second A&R Certificate of Incorporation").
- 5. That the Board of Directors of this corporation duly adopted resolutions proposing to amend and restate the Second A&R Certificate of Incorporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Second A&R Certificate of Incorporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is Harmony Biosciences II, Inc. (the "Corporation").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 423,630,000 shares of Common Stock, \$0.00001 par value per share ("**Common Stock**"), and (ii) 319,630,000 shares of Preferred Stock, \$0.00001 par value per share ("**Preferred Stock**").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

- 1. <u>General</u>. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.
- 2. <u>Voting</u>. Each holder of the Common Stock is entitled to one (1) vote for each share of Common Stock held by such holder at all meetings of stockholders (and written actions in lieu of meetings); <u>provided</u>, <u>however</u>, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Third Amended and Restated Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Third Amended and Restated Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of this Third Amended and Restated Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

286,000,000 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series A Preferred Stock," 8,030,000 shares of the authorized Preferred Stock of the Corporation are hereby designated "Series B Preferred Stock" and 25,600,000 shares of the authorized Preferred Stock of the Corporation are hereby designated "Series C Preferred Stock," each with the following applicable rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

1. Dividends. From and after the date of the issuance of any shares of Preferred Stock, dividends at the rate per annum of ten percent (10%) of the (x) Series A Original Issue Price (as defined below) with respect to the Series A Preferred Stock, (y) Series B Original Issue Price (as defined below) with respect to the Series B Preferred Stock and (z) Series C Original Issue Price (as defined below) with respect to the Series C Preferred Stock, in each case, compounded annually, shall accrue on such shares of Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock) (the "Accruing Dividends"). The Accruing Dividends shall accrue from day to day, whether or not declared, and shall be cumulative; provided, however, that except as set forth in the following sentence of this Section 1 or in Subsection 2.1 and Section 6, the Accruing Dividends shall be payable only when, as and if declared by the Board of Directors of the Corporation, and the Corporation shall be under no obligation to pay any Accruing Dividends. The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Third Amended and Restated Certificate of Incorporation) the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the greater of (i) the sum of the (A) Series A Original Issue Price with respect to the Series A Preferred Stock, (B) Series B Original Issue Price with respect to the Series B Preferred Stock and (C) Series C Original Issue Price with respect to the Series C Preferred Stock plus the amount of the aggregate Accruing Dividends then accrued on such share of Preferred Stock and not previously paid (the aggregate amount described in this clause (i), the "Preferred Return"), and (ii) (A) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of a share of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the (x) Series A Original Issue Price with respect to the Series A Preferred Stock, (y) Series B Original Issue Price with respect to the Series B Preferred Stock and (z) Series C Original Issue Price with respect to the Series C Preferred Stock; provided, that if, prior to the date of such dividend, the Corporation has declared, made or set aside any payment in respect of the Preferred Return, then, prior to any dividend being paid to the holders of the Preferred Stock pursuant to clause (ii) of this Section 1, each holder of shares of Common Stock (other than Common Stock issued upon the conversion of the Preferred Stock) shall receive with respect to each share of Common Stock held by such holder as of immediately prior to the distribution pursuant to clause (ii) of this Section 1 an amount equal to (x) the aggregate amount of such dividends in respect of the

Preferred Return divided by (y) the total number of shares of Common Stock issuable upon conversion of the Preferred Stock held by the holders of the shares of Preferred Stock as of immediately prior to the distribution pursuant to clause (ii) of this Section 1; provided, further, that if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, then the dividend payable to the holders of Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Preferred Stock dividend. The "Series A Original Issue Price" shall mean \$1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock. The "Series C Original Issue Price" shall mean \$1.96 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock. As used in this Third Amended and Restated Certificate of Incorporation, the term "Original Issue Price" means the Series A Original Issue Price, the Series B Original Issue Price or the Series C Original Issue Price, as applicable.

2. <u>Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.</u>

2.1 Preferential Payments to Holders of Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the holders of shares of Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Preferred Return, or (ii) such amount per share as would have been payable had all shares of Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable pursuant to this sentence is hereinafter referred to as the "Preferred Liquidation Amount"); provided, that if, prior to any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the Corporation has declared, made or set aside any payment in respect of the Preferred Return, then, prior to any dividends being paid to the holders of the shares of Preferred Stock pursuant to clause (ii) of this Subsection 2.1, the holders of the Common Stock (other than Common Stock issued upon the conversion of the Preferred Stock) shall receive in respect of each share of Common Stock then held by such holder an amount equal to (x) the aggregate amount of such dividend in respect of the Preferred Return divided by (y) the total number of shares of Common Stock issuable upon conversion of the Preferred Stock held by the holders of the shares of Preferred Stock as of immediately prior to such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event. If, upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, then the holders of shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 <u>Payments to Holders of Common Stock</u>. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder.

2.3 Deemed Liquidation Events.

- 2.3.1 <u>Definition</u>. Each of the following events shall be considered a **"Deemed Liquidation Event"** unless the holders of a majority of the outstanding shares of Preferred Stock elect otherwise by written notice sent to the Corporation at least ten (10) days prior to the effective date of any such event:
 - (a) a merger or consolidation in which
 - (i) the Corporation is a constituent party or
 - (ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in <u>Subsection 2.3.1(a)</u> (j) unless the agreement or plan of

merger or consolidation for such transaction (the "Merger Agreement") provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

- (b) In the event of a Deemed Liquidation Event referred to in <u>Subsection 2.3.1(a)(ii)</u> or <u>2.3.1(b)</u>, if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the holders of a majority of the then outstanding shares of Preferred Stock so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "Available **Proceeds"**), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share equal to the Preferred Liquidation Amount, Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall ratably redeem each holder's shares of Preferred Stock to the fullest extent of such Available Proceeds, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. The provisions of Section 6 shall apply, with such necessary changes in the details thereof as are necessitated by the context, to the redemption of the Preferred Stock pursuant to this Subsection 2.3.2(b). Prior to the distribution or redemption provided for in this Subsection 2.3.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.
- 2.3.3 <u>Amount Deemed Paid or Distributed</u>. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. The value of such property, rights or securities shall be determined in good faith by the Board of Directors of the Corporation.
- 2.3.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event pursuant to Subsection 2.3.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is deposited into an escrow account, is retained as holdback or is otherwise payable only upon satisfaction of contingencies (the "Additional Consideration"), then the Merger Agreement shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "Initial Consideration") shall be allocated among the holders of capital stock of the Corporation in

accordance with <u>Subsections 2.1</u> and <u>2.2</u> as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event, and (b) any Additional Consideration that becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with <u>Subsections 2.1</u> and <u>2.2</u> after taking into account the previous payment of the Initial Consideration as part of the same transaction . For the purposes of this <u>Subsection 2.3.4</u>, consideration placed into escrow or retained as holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Additional Consideration.

3. Voting

- 3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock Shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Third Amended and Restated Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class.
- 3.2 <u>Election of Directors</u>. The holders of record of the shares of Preferred Stock, exclusively and as a separate class, shall be entitled to elect six (6) directors of the Corporation and the holders of record of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect two (2) directors of the Corporation. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Preferred Stock or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Preferred Stock or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this **Subsection 3.2**.

- 3.3 <u>Preferred Stock Protective Provisions</u>. For so long as at least 44,236,730 shares of Preferred Stock (which number is subject to appropriate adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding, the Corporation shall not, either directly or indirectly through a subsidiary of the Corporation, as applicable, or by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Third Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect.
- 3.3.1 amend, alter or repeal any provision of (i) this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation or (ii) the governing documents of any of its subsidiaries;
- 3.3.2 create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption;
- 3.3.3 (i) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Preferred Stock in respect of any such right, preference or privilege or (ii) reclassify, alter or amend any existing security of the Corporation that is junior to the Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption,, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Preferred Stock in respect of any such right, preference or privilege;
- 3.3.4 modify, amend or waive the rights, preferences or privileges of the holders of the shares of Preferred Stock under this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation in a manner that would materially and adversely affect the holders of the shares of Preferred Stock;
- 3.3.5 create, or authorize the creation of, or issue, or authorize the issuance of any debt security, or permit any subsidiary to take any such action with respect to any debt security, unless such debt security has received the prior approval of the Board of Directors of the Corporation;
 - 3.3.6 increase or decrease the authorized number of directors constituting the Board of Directors of the Corporation;
- 3.3.7 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event,

enter into any agreement with respect to any transaction or series of related transactions in which one or more independent third parties acquire (whether by merger, consolidation, sale, lease, exclusive license, exclusive marketing or distribution, recapitalization, transfer, exchange or other distribution or disposition) more than fifty percent (50%) of (i) the outstanding voting power of the Corporation or any of its subsidiaries (provided that, in the case of a sale of the equity of any of the Corporation's subsidiaries, the equity of such subsidiary or subsidiaries constitutes substantially all of the Corporation's assets determined on a consolidated basis, or consent to any of the foregoing;

- 3.3.8 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on the Preferred Stock as expressly authorized herein and (ii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service pursuant to the terms and conditions of the applicable award or other agreement or any equity incentive plan, agreement or arrangement approved by the Board of Directors of the Corporation;
- 3.3.9 waive the requirement to make any liquidation distribution resulting from any Deemed Liquidation Event in accordance with the terms and conditions set forth in this Third Amended and Restated Certificate of Incorporation; <u>provided</u>, that in no event shall such waiver reduce the amount of any distributions in respect of the shares of Preferred Stock that would ultimately be paid;
- 3.3.10 except for agreements or arrangements on arms'-length terms, enter into any agreement or arrangement with any person or entity controlling, controlled by or under common control with (i) the Corporation or (ii) any holder of shares of capital stock of the Corporation; provided, that no such consent or vote shall be required in connection with (x) that certain Management Agreement, dated as of September 22, 2017, by and between the Corporation and Paragon Biosciences, LLC (but excluding any amendments to such agreement, which do require consent), (y) any issuance of equity securities under any equity incentive plan, agreement or arrangement approved by the Board of Directors of the Corporation or (z) the entry by the Corporation into any employment agreement with any individual who solely holds options to purchase shares of capital stock of the Corporation or restricted capital stock of the Corporation so long as such employment agreement has been approved by the Board of Directors of the Corporation; or
- 3.3.11 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary.
- 3.4 <u>Series A Preferred Stock Protective Provisions.</u> For so long as at least 39,583,000 shares of Series A Preferred Stock (which number is subject to appropriate

adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding, the Corporation shall not, either directly or indirectly through a subsidiary of the Corporation, as applicable, or by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Third Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series A Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

- 3.4.1 modify, amend or waive the rights, preferences or privileges of the holders of the shares of Series A Preferred Stock under this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation in a manner that would have a material and adverse effect on the holders of the shares of Series A Preferred Stock that is different from any material and adverse effect on the holders of the shares of Series B Preferred Stock.
- 3.5 Series B Preferred Stock Protective Provisions. For so long as at least 1,111,000 shares of Series B Preferred Stock (which number is subject to appropriate adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding, the Corporation shall not, either directly or indirectly through a subsidiary of the Corporation, as applicable, or by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Third Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:
- 3.5.1 modify, amend or waive the rights, preferences or privileges of the holders of the shares of Series B Preferred Stock under this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation in a manner that would have a material and adverse effect on the holders of the shares of Series B Preferred Stock that is different from any material and adverse effect on the holders of the shares of Series A Preferred Stock.
- 3.6 Series A and B Preferred Stock Protective Provisions. For so long as an aggregate of at least 40,694,000 shares of Series A Preferred Stock and Series B Preferred Stock (which number is subject to appropriate adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding, the Corporation shall not, either directly or indirectly through a subsidiary of the Corporation, as applicable, or by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Third Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series A Preferred Stock and Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class, and any such act or

transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

- 3.6.1 modify, amend or waive the rights, preferences or privileges of the holders of the shares of Series A Preferred Stock and Series B Preferred Stock under this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation in a manner that would have a material and adverse effect on the holders of the shares of Series A Preferred Stock and Series B Preferred Stock that is different from any material and adverse effect on the holders of the shares of Series C Preferred Stock.
- 3.7 Series C Preferred Stock Protective Provisions. For so long as at least 3,542,730 shares of Series C Preferred Stock (which number is subject to appropriate adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding, the Corporation shall not, either directly or indirectly through a subsidiary of the Corporation, as applicable, or by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Third Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series C Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:
- 3.7.1 modify, amend or waive the rights, preferences or privileges of the holders of the shares of Series C Preferred Stock under this Third Amended and Restated Certificate of Incorporation or Bylaws of the Corporation in a manner that would have a material and adverse effect on the holders of the shares of Series C Preferred Stock that is different from any material and adverse effect on the holders of the shares of Series A Preferred Stock and Series B Preferred Stock.

4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the "Conversion Rights"):

4.1 Right to Convert.

4.1.1 <u>Conversion Ratio</u>. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined (a) in the case of both the Series A Preferred Stock and the Series B Preferred Stock, by dividing the Series A Original Issue Price by the applicable Preferred Conversion, and (b) in the case of the Series C Preferred Stock, by dividing the Series C Original Issue Price by the applicable Preferred Conversion Price (as defined below) in effect at the time of conversion. The "Preferred Conversion Price" applicable to the Series A Preferred Stock and the Series B Preferred Stock shall initially be equal to \$1.00 (such Preferred Conversion Price, the "Series A/B Conversion Price"). The "Preferred Conversion Price" applicable to

the Series C Preferred Stock shall initially be equal to the Series C Original Issue Price (such Preferred Conversion Price, the "Series C Conversion Price"). Such initial Preferred Conversion Prices, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

- 4.1.2 <u>Termination of Conversion Rights</u>. In the event of a notice of redemption of any shares of Preferred Stock pursuant to <u>Section 6</u>, the Conversion Rights of the shares designated for redemption shall terminate at the close of business on the last full day preceding the date fixed for redemption, unless the redemption price is not fully paid on such redemption date, in which case the Conversion Rights for such shares shall continue until such price is paid in full. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.
- 4.2 <u>Fractional Shares</u>. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder's shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "Conversion Time"), and the shares of Common Stock issuable upon conversion of the specified shares shall

be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of the Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in <u>Subsection 4.2</u> in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

- 4.3.2 Reservation of Shares. The Corporation shall at all times when the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock. If, at any time, the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, then the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Third Amended and Restated Certificate of Incorporation. Before taking any action that would cause an adjustment reducing the applicable Preferred Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Preferred Stock, the Corporation will take any corporate action that may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Preferred Conversion Price.
- 4.3.3 Effect of Conversion. All shares of Preferred Stock that have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2 and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.
- 4.3.4 <u>No Further Adjustment</u>. Upon any such conversion, no adjustment to the applicable Preferred Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.
- 4.3.5 <u>Taxes</u>. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this <u>Section 4</u>. The Corporation shall not, however, be required to pay any tax which may be payable in respect of

any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

- 4.4 Adjustments to Preferred Conversion Price for Diluting Issues.
 - 4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:
- (a) **"Option"** shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.
 - (b) "Series C Original Issue Date" shall mean August 9, 2019.
- (c) **"Convertible Securities"** shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.
- (d) **"Additional Shares of Common Stock"** shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series C Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, **"Exempted Securities"):**
 - (i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Preferred Stock;
 - (ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by <u>Subsection 4.5</u>, <u>4.6</u>, <u>4.7</u> or <u>4.8</u>;
 - (iii) up to 35,496,000 shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to any plan, agreement or arrangement approved by the Board of Directors of the Corporation;
 - (iv) shares of Common Stock or Convertible Securities actually issued upon the exercise

- of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security; or
- (v) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors of the Corporation.

For the avoidance of doubt, in the case of clauses (iii) and (v) above, shares issued to Affiliates (as defined below) of the Corporation shall not be deemed to be Exempted Securities. An "Affiliate" of a person shall mean any other person who, directly or indirectly, controls, is controlled by, or is under common control with such first person.

4.4.2 <u>No Adjustment of Preferred Conversion Price</u>. No adjustment to a Preferred Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of the applicable series of Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series C Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, pursuant to the terms of <u>Subsection 4.4.4</u>, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of

such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the Series A/B Conversion Price and the Series C Conversion Price, as the case may be, computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to the Series A/B Conversion Price and the Series C Conversion Price, respectively, as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Preferred Conversion Price applicable to such series of Preferred Stock to an amount which exceeds the lower of (i) the Preferred Conversion Price applicable to such series that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the applicable Preferred Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series C Original Issue Date), are revised after the Series C Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, pursuant to the terms of <u>Subsection 4.4.4</u>, such Preferred Conversion Price shall be readjusted to the Preferred Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, then any adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 <u>Adjustment of Preferred Conversion Price Upon Issuance of Additional Shares of Common Stock</u>. In the event the Corporation shall at any time after the Series C Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to <u>Subsection 4.4.3</u>), without consideration or for a consideration per share less than the Series A/B Conversion Price (in the case of the Series A Preferred Stock and the Series B Preferred Stock) or the Series C Conversion Price (in the case of the Series C Preferred Stock) in effect immediately prior to such issue, then the Series A/B Conversion Price and/or the Series C Conversion Price, as applicable, shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

 $(a) \ \ ^{\circ}CP_{2}"\ shall\ mean\ the\ applicable\ Preferred\ Conversion\ Price\ in\ effect\ immediately\ after\ such\ issue\ of\ Additional$

(b) "CP1" shall mean the applicable Preferred Conversion Price in effect immediately prior to such issue of Additional

Shares of Common Stock;

Shares of Common Stock

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

- (d) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to CP_1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP_1); and
 - (e) "C" shall mean the number of such Additional Shares of Common Stock issued in such transaction.
- 4.4.5 <u>Determination of Consideration</u>. For purposes of this <u>Subsection 4.4</u>, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:
 - (a) <u>Cash and Property</u>: Such consideration shall:
 - (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;
 - (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation; and
 - (iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation.

(b) <u>Options and Convertible Securities</u>. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to <u>Subsection 4.4.3</u>, relating to Options and Convertible Securities, shall be determined by dividing:

- (i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by
- (ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 <u>Multiple Closing Dates</u>. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Series A/B Conversion Price or the Series C Conversion Price, as the case may be, pursuant to the terms of <u>Subsection 4.4.4</u>, and such issuance dates occur within a period of no more than ninety (90) days from the first such issuance to the final such issuance, then, upon the final such issuance, the Series A/B Conversion Price and/or the Series C Conversion Price, as the case may be, shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series C Original Issue Date effect a subdivision of the outstanding Common Stock, then each Preferred Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of each such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series C Original Issue Date combine the outstanding shares of Common Stock, then each Preferred Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of each such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 <u>Adjustment for Certain Dividends and Distributions</u>. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event each Preferred Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying each such Preferred Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing, (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, then each Preferred Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter each Preferred Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions, and (b) no such adjustment shall be made with respect to a given series of Preferred Stock if the holders of such series of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of such series of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 <u>Adjustment for Merger or Reorganization, etc.</u> Subject to the provisions of <u>Subsection 2.3</u>, if there shall occur any reorganization, recapitalization, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by <u>Subsections 4.4</u>, <u>4.6</u> or <u>4.7</u>), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of any series of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of such series of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this <u>Section 4</u> with respect to the rights and interests thereafter of the holders of such series of Preferred Stock, to the end that the provisions set forth in this <u>Section 4</u> (including provisions with respect to changes in and other adjustments of the Preferred Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of such series of Preferred Stock. For the avoidance of doubt, nothing in this <u>Subsection 4.8</u> shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights to which they are otherwise entitled under the DGCL in connection with a merger triggering an adjustment hereunder, nor shall this <u>Subsection 4.8</u> be deemed conclusive evidence of the fair value of t

4.9 <u>Certificate as to Adjustments</u>. Upon the occurrence of each adjustment or readjustment of a Preferred Conversion Price pursuant to this <u>Section 4</u>, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than thirty (30) days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of the applicable series of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which such Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of any such Preferred Stock (but in any event not later than thirty (30) days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) each applicable Preferred Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of such series of Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

the Corporation will, in each such case, send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Preferred Stock and the Common Stock. Such notice shall be sent at least thirty (30) days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 <u>Trigger Events</u>. Upon the closing of the sale of shares of Common Stock to the public at a price of at least \$3.92 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$100,000,000 of gross proceeds, net of underwriting discounts and commissions, to the Corporation (the time of such closing is referred to herein as the "Mandatory Conversion Time"), (a) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to <u>Subsection 4.1.1</u>, (b) such shares may not be reissued by the Corporation and (c) the Corporation shall, as determined by the Board of Directors of the Corporation in its sole discretion, either (i) issue to each holder of shares of Preferred Stock as of immediately prior to the Mandatory Conversion Time a number of shares of Common Stock equal to (x) the aggregate amount of Accruing Dividends accrued on the shares of Preferred Stock held by such holder and not previously paid as of immediately prior to the Mandatory Conversion Time <u>divided by</u> (y) the actual price per share of Common Stock in such sale of shares of Common Stock to the public, or (ii) pay to each holder of shares of Preferred Stock in cash an aggregate amount equal to the aggregate Accruing Dividends accrued on the shares of Preferred Stock held by such holder and not previously paid as of immediately prior to the Mandatory Conversion Time.

5.2 <u>Procedural Requirements</u>. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this <u>Section 5</u>. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft

or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof (including Subsection 5.1(c), if applicable), and (b) pay cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion, and as provided in Subsection 5.1(c), if applicable. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. Redemption.

6.1 General. Unless prohibited by Delaware law governing distributions to stockholders, at any time on or after the later of (x) September 22, 2021 and (y) the date that is ninety-one (91) days following the date on which all amounts outstanding under (i) that certain Term Loan Agreement, dated as of February 28, 2019, by and among the Corporation, Harmony Biosciences, LLC, as the borrower, the financial institutions from time to time party thereto, as lenders, and CRG Servicing LLC, as administrative agent and collateral agent for such lender, as amended, restated, supplemented or otherwise modified from time to time in accordance with the terms thereof, (ii) any other loan agreement to which the Corporation or any subsidiary of the Corporation is a party and pursuant to which any person has committed to provide debt financing to the Corporation or any subsidiary of the Corporation, as amended, restated, supplemented or otherwise modified from time to time in accordance with the terms thereof and (iii) any extensions, renewals, refinancings or replacements of any of the foregoing, have been repaid in full and all commitments to provide debt financing thereunder have terminated, the Corporation shall redeem all shares of Preferred Stock at a price per share equal to (A) (i) the Series A Original Issue Price with respect to the Series A Preferred Stock, (ii) the Series B Original Issue Price with respect to the Series B Preferred Stock and (iii) the Series C Original Issue Price with respect to the Series B Preferred Stock plus (B) the amount of the aggregate Accruing Dividends then accrued on such share of Preferred Stock and not previously paid as of the date of the Corporation's receipt of the Redemption Request (the "Redemption Price"). The closing of any redemption pursuant to this Subsection 6.1 shall be effective as of a date (the "Redemption Date") not less than 180 days following receipt by the Corporation of written notice from the holders (the "Requesting Holders") of a majority of the then outstandin

"Redemption Request"). Upon receipt of a Redemption Request, the Corporation shall apply all of its assets to any such redemption, and to no other corporate purpose, except to the extent prohibited by Delaware law governing distributions to stockholders. On the Redemption Date, the Corporation shall redeem all of the issued and outstanding shares of Preferred Stock. If, on the Redemption Date, Delaware law governing distributions to stockholders prevents the Corporation from redeeming all shares of Preferred Stock, then the Corporation shall ratably redeem the maximum number of shares that it may redeem consistent with such law, and shall redeem the remaining shares as soon as it may lawfully do so under such law. For the avoidance of doubt, a holder of shares of Preferred Stock shall maintain its rights, preferences and privileges with respect to such shares under this Third Amended and Restated Certificate of Incorporation until such time as such shares have been redeemed by the Corporation in accordance with this Section 6.

6.2 <u>Redemption Notice</u>. The Corporation shall send written notice of the mandatory redemption (the **"Redemption Notice"**) to each holder of record of Preferred Stock not less than forty (40) days prior to the Redemption Date. Each Redemption Notice shall state:

- (a) the number of shares of Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice;
 - (b) the Redemption Date and the Redemption Price;
 - (c) the date upon which the holder's right to convert such shares terminates (as determined in accordance with

Subsection 4.1); and

(d) for holders of shares in certificated form, that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Preferred Stock to be redeemed.

If the Corporation receives, on or prior to the twentieth (20th) day after the date of delivery of the Redemption Notice to a holder of Preferred Stock, written notice from such holder that such holder elects to be excluded from the redemption provided in this <u>Section 6</u>, then the shares of Preferred Stock registered on the books of the Corporation in the name of such holder at the time of the Corporation's receipt of such notice shall thereafter be "Excluded Shares." Excluded Shares shall not be redeemed or redeemable pursuant to this <u>Section 6</u>, whether on the Redemption Date or thereafter. Notwithstanding the foregoing, no Requesting Holder may so elect to be excluded from the redemption provided in this Section 6.

6.3 <u>Surrender of Certificates; Payment</u>. On or before the Redemption Date, each holder of shares of Preferred Stock to be redeemed on the Redemption Date, unless such holder has exercised his, her or its right to convert such shares as provided in <u>Section 4</u>, shall, if a holder of shares in certificated form, surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the

Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the applicable Redemption Price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate, instrument or book entry representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

- 6.4 <u>Rights Subsequent to Redemption</u>. If the Redemption Notice shall have been duly given, and if on the Redemption Date the applicable Redemption Price payable upon redemption of the shares of Preferred Stock to be redeemed on the Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that any certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to accrue after the Redemption Date and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of any such certificate or certificates therefor.
- 7. <u>Redeemed or Otherwise Acquired Shares</u>. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.
- 8. <u>Waiver</u>. Any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the holders of a majority of the shares of Preferred Stock then outstanding.
- 9. <u>Notices</u>. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.
- **FIFTH:** Subject to any additional vote required by this Third Amended and Restated Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors of the Corporation is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

SIXTH: Subject to any additional vote required by this Third Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation.

SEVENTH: Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors of the Corporation or in the Bylaws of the Corporation.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: The following indemnification provisions shall apply to the persons enumerated below.

- 1. <u>Right to Indemnification of Directors and Officers</u>. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "Indemnified Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys" fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article Tenth, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors of the Corporation.
- 2. <u>Prepayment of Expenses of Directors and Officers</u>. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, <u>provided</u>, <u>however</u>, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article Tenth or otherwise.

- 3. <u>Claims by Directors and Officers</u>. If a claim for indemnification or advancement of expenses under this Article Tenth is not paid in full within thirty (30) days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.
- 4. <u>Indemnification of Employees and Agents</u>. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors of the Corporation in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors of the Corporation.
- 5. <u>Advancement of Expenses of Employees and Agents</u>. The Corporation may pay the expenses (including attorneys' fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors of the Corporation.
- 6. <u>Non-Exclusivity of Rights</u>. The rights conferred on any person by this Article Tenth shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of this Third Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation or by agreement, vote of stockholders or disinterested directors or otherwise.
- 7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.
- 8. <u>Insurance</u>. The Board of Directors of the Corporation may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article

Tenth; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Tenth.

9. <u>Amendment or Repeal</u>. Any repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "Excluded Opportunity" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, "Covered Persons"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or this Third Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery, or for which the days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the

THIRTEENTH: For purposes of Section 500 of the California Corporations Code (to the extent applicable), in connection with any repurchase of shares of Common Stock permitted under this Third Amended and Restated Certificate of Incorporation from employees, officers, directors or consultants of the Corporation in connection with a termination of employment or services pursuant to agreements or arrangements approved by the Board of Directors of the Corporation (in addition to any other consent required under this this Third Amended and Restated Certificate of Incorporation), such repurchase may be made without regard to any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined in Section 500 of the California Corporations Code), Accordingly, for purposes of making any calculation under California Corporations Code Section 500 in connection with such repurchase, the amount of any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined therein) shall be deemed to be zero (0).

* * *

- **6.** That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.
- 7. That this Third Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law,

[Signature Page Follows]

IN WITNESS WHEREOF, this Third Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this <u>9th</u> day of August, 2019.

By: /s/ Andrew Serafin

Andrew Serafin, Assistant Secretary

CERTIFICATE OF AMENDMENT TO THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF HARMONY BIOSCIENCES II, INC.

(Originally Incorporated on July 25, 2017)

The undersigned, being the Chief Executive Officer of Harmony Biosciences II, Inc., a corporation (the "Corporation") organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), does certify as follows:

FIRST: That the Board of Directors of the Corporation, pursuant to unanimous written consent and in accordance with Sections 141 (f) and 242 of the General Corporation Law of the State of Delaware, adopted a resolution setting forth an amendment to the Third Amended and Restated Certificate of Incorporation of the Corporation set forth below (the "Amendment").

SECOND: That in accordance with Sections 228 and 242 of the General Corporation Law of the State of Delaware, the Amendment was duly adopted and approved pursuant to a written consent signed by the holders of a majority of the issued and outstanding shares of Common Stock of the Corporation, the holders of a majority of the issued and outstanding shares of Series C Preferred Stock, the holders of a majority of the issued and outstanding shares of Series A Preferred Stock of the Corporation, Series B Preferred Stock of the Corporation and Series C Preferred Stock of the Corporation and the holders of a majority of the issued and outstanding shares of voting stock of the Corporation.

THIRD: Immediately upon the effectiveness of the Amendment and without further action by the Corporation or any holders thereof, the first paragraph of Article Fourth of the Third Amended and Restated Certificate of Incorporation of the Corporation shall be amended and restated in its entirety to read as follows:

The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 424,000,000 shares of Common Stock, \$0.00001 par value per share ("Common Stock"), and (ii) 323,030,000 shares of Preferred Stock, \$0.00001 par value per share ("Preferred Stock").

FOURTH: The first paragraph of Section B of Article Fourth of the Third Amended and Restated Certificate of Incorporation shall be amended and restated in its entirety as follows:

286,000,000 shares of the authorized Preferred Stock of the Corporation are hereby designated "Series A Preferred Stock," 8,030,000 shares of the authorized Preferred Stock of the Corporation are hereby designated "Series B Preferred Stock" and 29,000,000 shares of the authorized Preferred Stock of the Corporation are hereby designated "Series C Preferred Stock," each with the following applicable rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned, being the Chief Executive Officer of the Corporation hereinabove named, for the purpose of amending the Third Amended and Restated Certificate of Incorporation of the Corporation pursuant to the General Corporation Law of the State of Delaware, under penalties of perjury does hereby declare and certify that this is the act and deed of the Corporation and the facts stated herein are true, and accordingly has hereunto signed this Certificate of Amendment to Third Amended and Restated Certificate of Incorporation this <u>8</u> day of January, 2020.

/s/ John Jacobs

Name: John Jacobs

Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT TO THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF HARMONY BIOSCIENCES II, INC.

(Originally Incorporated on September 19, 2017)

The undersigned, being the Chief Executive Officer of Harmony Biosciences II, Inc., a corporation (the "Corporation") organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), does certify as follows:

FIRST: That the Board of Directors of the Corporation, pursuant to unanimous written consent and in accordance with Sections 141(f) and 242 of the General Corporation Law of the State of Delaware, adopted a resolution setting forth an amendment to the Third Amended and Restated Certificate of Incorporation of the Corporation set forth below (the "Amendment").

SECOND: That in accordance with Sections 228 and 242 of the General Corporation Law of the State of Delaware, the Amendment was duly adopted and approved pursuant to a written consent signed by the holders of a majority of the issued and outstanding shares of Series A Preferred Stock of the Corporation, Series B Preferred Stock of the Corporation and Series C Preferred Stock of the Corporation, voting as a class.

THIRD: Immediately upon the effectiveness of the Amendment and without further action by the Corporation or any holders thereof, Article First of the Third Amended and Restated Certificate of Incorporation of the Corporation shall be amended and restated in its entirety to read as follows:

The name of this corporation is Harmony Biosciences Holdings, Inc. (the "Corporation").

[Signature page follows]

IN WITNESS WHEREOF, the undersigned, being the President and Chief Executive Officer of the Corporation hereinabove named, for the purpose of amending the Third Amended and Restated Certificate of Incorporation of the Corporation pursuant to the General Corporation Law of the State of Delaware, under penalties of perjury does hereby declare and certify that this is the act and deed of the Corporation and the facts stated herein are true, and accordingly has hereunto signed this Certificate of Amendment to Third Amended and Restated Certificate of Incorporation this 31st day of January, 2020.

/s/ John Jacobs

John Jacobs, President and Chief Executive Officer

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Execution Version

CREDIT AGREEMENT

dated as of January 9, 2020

among

HARMONY BIOSCIENCES, LLC,

as the Borrower,

THE LENDERS FROM TIME TO TIME PARTY HERETO

and

ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP,

as the Administrative Agent

THE LOANS ARE DEEMED TO BE MADE WITH ORIGINAL ISSUE DISCOUNT FOR U.S. FEDERAL INCOME TAX PURPOSES. REQUESTS FOR INFORMATION REGARDING THE ISSUE PRICE, AMOUNT OF ORIGINAL ISSUE DISCOUNT, ISSUE DATE AND YIELD TO MATURITY ON THE LOANS MAY BE DIRECTED TO THE BORROWER CARE OF CHIEF FINANCIAL OFFICER OF HARMONY BIOSCIENCES, LLC AT 630 W GERMANTOWN PIKE, PLYMOUTH MEETING, PA 19462.

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CREDIT AGREEMENT

THIS CREDIT AGREEMENT dated as of January 9, 2020 (as amended, supplemented or otherwise modified from time to time, this "Agreement"), is among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "Borrower"), the Lenders (defined herein) and ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its Affiliates, successors, transferees and assignees), as Administrative Agent. The Borrower, the Administrative Agent and each Lender are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WITNESSETH:

WHEREAS, the Borrower has requested that the Lenders provide a senior term loan facility to the Borrower in an aggregate principal amount of \$200,000,000 available at the Closing, subject to the terms and conditions set forth herein); and

WHEREAS, the Lenders are willing, on the terms and subject to the conditions hereinafter set forth, to extend the Commitment and make the Loans to the Borrower;

NOW, THEREFORE, the parties hereto agree as follows.

ARTICLE I DEFINITIONS AND ACCOUNTING TERMS

SECTION 1.1 <u>Defined Terms</u>. The following terms (whether or not underscored) when used in this Agreement, including its preamble and recitals, shall, except where the context otherwise requires, have the following meanings (such meanings to be equally applicable to the singular and plural forms thereof):

"Acquisition" is defined in the definition of "Permitted Acquisition".

- "<u>Administrative Agent</u>" means OrbiMed Royalty & Credit Opportunities III, LP, in its capacity as administrative agent under any of the Loan Documents, or any successor administrative agent.
- "<u>Administrative Agent's Office</u>" means the Administrative Agent's address and, as appropriate, account as set forth on Schedule 10.2 or such other address or account as the Administrative Agent may from time to time notify the Borrower and the Lenders.
 - "Administration Fee" is defined in Section 3.11.

"Affiliate" of any Person means any other Person which, directly or indirectly, Controls, is Controlled by or is under common Control with such Person. "Control" (and its correlatives) by any Person means (i) the power of such Person, directly or indirectly, (x) to vote 15% or more of the Voting Securities (determined on a fully diluted basis) of another Person, or (y) to direct or cause the direction of the management and policies of such other Person (whether by contract or otherwise), and/or (ii) the ownership by such Person of 15% or more of the Capital Securities of another Person.

- "Agreement" is defined in the preamble.
- "Applicable Margin" means 11.00%.
- "<u>Applicable Percentage</u>" means, with respect to any Lender at any time, with respect to such Lender's portion of the outstanding Loans at any time, the percentage of the outstanding principal amount of the Loans held by such Lender at such time. The initial Applicable Percentage of each Lender is set forth opposite the name of such Lender on <u>Schedule 2.1</u> or in the Assignment and Assumption pursuant to which such Lender becomes a party hereto, as applicable.
- "Approved Fund" means any Fund that is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) an entity or an Affiliate of an entity that administers or manages a Lender.
- "<u>Assignment and Assumption</u>" means an assignment and assumption entered into by a Lender and an Eligible Assignee (with the consent of any party whose consent is required by <u>Section 10.10(b)</u>), and accepted by the Administrative Agent, in substantially the form of <u>Exhibit F</u> hereto or any other form approved by the Administrative Agent.
 - "Assignment Effective Date" is defined in Section 10.10(a).
- "Authorized Officer" means, relative to Holdings, the Borrower or any of the Subsidiaries, those of its officers, general partners or managing members (as applicable) whose signatures and incumbency shall have been certified to the Administrative Agent and the Lenders pursuant to Section 5.2.
- "Benefit Plan" means any employee benefit plan, as defined in section 3(3) of ERISA, that either: (i) is a "multiemployer plan," as defined in section 3(37) of ERISA, (ii) is subject to section 412 of the Code, section 302 of ERISA or Title IV of ERISA, (iii) provides welfare benefits to terminated employees, other than to the extent required by section 4980B(f) of the Code and the corresponding provisions of ERISA, or (iv) provides medical, dental, vision, or long-term disability benefits and is not fully insured by a third-party insurance company.
- "Bioprojet" means Bioprojet Société Civile de Recherche, an independent (privately owned) research company organized under the laws of France, together with its Affiliates, including Bioprojet Pharma SARL and Bioprojet Europe Ltd.
- "Bona Fide Debt Fund" means any bona fide debt fund, investment vehicle, regulated banking entity or non-regulated lending entity that is primarily engaged in, or advises funds or other investment vehicles that are primarily engaged in, making, purchasing, holding or otherwise investing in commercial loans or bonds and/or similar extensions of credit in the ordinary course of business.
 - "Borrower" is defined in the preamble.
- "Business Day" means any day which is neither a Saturday or Sunday nor a legal holiday on which banks are authorized or required to be closed in New York. New York.

"<u>Capital Securities</u>" means, with respect to any Person, all shares of, interests or participations in, or other equivalents in respect of (in each case however designated, whether voting or non-voting), of such Person's capital stock, and any warrants, options or other rights entitling the holder thereof to purchase or acquire any such capital stock, in each case, whether now outstanding or issued after the Closing Date.

"Capitalized Lease Liabilities" means, with respect to any Person, all monetary obligations of such Person and its Subsidiaries under any leasing or similar arrangement which have been (or, in accordance with GAAP, should be) classified as capitalized leases, and for purposes of each Loan Document the amount of such obligations shall be the capitalized amount thereof, determined in accordance with GAAP, and the stated maturity thereof shall be the date of the last payment of rent or any other amount due under such lease prior to the first date upon which such lease may be terminated by the lessee without payment of a premium or a penalty; provided, that for all purposes of this Agreement (other than with respect to the preparation of audited or unaudited financial statements), all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP but for the effectiveness of FASB ASC 842 shall continue to be accounted for as operating leases for purposes of all financial definitions and calculations for purpose of this Agreement (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with FASB ASC 842 (on a prospective or retroactive basis or otherwise) to be treated as Capitalized Lease Liabilities in the financial statements.

"Cash Equivalent Investment" means, at any time:

- (a) any direct obligation of (or unconditionally guaranteed by) the United States (or any agency or political subdivision thereof, to the extent such obligations are supported by the full faith and credit of the United States) maturing not more than one year after such time;
- (b) commercial paper maturing not more than one year from the date of issue, which is issued by a corporation (other than an Affiliate of Holdings, the Borrower or any of its Subsidiaries) organized under the laws of any state of the United States or of the District of Columbia and rated A-1 or higher by S&P or P-1 or higher by Moody's;
- (c) any certificate of deposit, demand or time deposit, overnight bank deposit or bankers' acceptance, maturing not more than one year after its date of issuance, which is issued by or placed with any bank or trust company organized under the laws of the United States (or any state thereof) and which has (x) a credit rating of A2 or higher from Moody's or A or higher from S&P and (y) a combined capital and surplus greater than \$500,000,000;
- (d) investments in money market mutual funds at least 95% of the assets of which are comprised of securities of the types described in <u>clauses (a)</u> through <u>(c)</u> of this definition; or

(e) in the case of Foreign Subsidiaries only, instruments equivalent to those referred to in clauses (a) through (d) above, in each case, denominated in any foreign currency comparable in credit quality and tenor to those referred to in such clauses above and customarily used by Persons for cash management purposes in any jurisdiction outside the United States to the extent reasonably required in connection with any business conducted by any Foreign Subsidiary organized in such jurisdiction.

"Casualty Event" means the damage, destruction or condemnation, as the case may be, of property of any Person or any of its Subsidiaries.

"cGCP" means the then current Good Clinical Practices that establish the national and international ethical and scientific quality standards for designing, conducting, recording and reporting clinical trials that are promulgated or endorsed for the United States by the FDA (including through ICH E6 and 21 CFR Parts 50, 54, 56 and 312 and applicable guidance documents) and for outside the United States by comparable Governmental Authorities.

"<u>cGMP</u>" means the then current good manufacturing practices and regulatory requirements for or concerning manufacturing practices for pharmaceutical and biological products (and components thereof) that are promulgated or endorsed for the United States by the FDA (including through 21 CFR Parts 210 and 211) and for outside the United States by comparable Governmental Authorities.

"Change in Control" means and shall be deemed to have occurred if (i) (A) Holdings shall cease to directly own, beneficially and of record, 100% of the issued and outstanding Capital Securities of the Borrower, (B) prior to the occurrence of a Qualified IPO, any "person" or "group" (within the meaning of Rule 13d-5 of the Exchange Act) other than the Valor Investors or the Paragon Investors, shall own, directly or indirectly, beneficially or of record, determined on a fully diluted basis, more than 35% of the Voting Securities of Holdings, (C) either the Valor Investors or the Paragon Investors, shall own, directly or indirectly, beneficially or of record, determined on a fully diluted basis, more than 45% of the Voting Securities of Holdings or (D) after the occurrence of a Qualified IPO, any "person" or "group" (within the meaning of Rule 13d-5 of the Exchange Act) other than the Valor Investors or the Paragon Investors shall own, directly or indirectly, beneficially or of record, determined on a fully diluted basis, more than 45% of the Voting Securities of Holdings; (ii) a majority of the seats (other than vacant seats) on the board of directors (or equivalent) of Holdings shall at any time be occupied by persons who were not directors on the Closing Date and who were neither (x) nominated by the board of directors of Holdings nor (y) appointed pursuant to and in accordance with the terms of the Voting Agreement, or (iii) any Subsidiary shall cease to be a wholly owned Subsidiary of the Borrower (except pursuant to a Disposition of all of the Capital Securities of a Subsidiary otherwise permitted hereunder); provided that the occurrence of a Qualified IPO shall not be deemed a Change in Control.

"Change in Law" means the occurrence, after the date of this Agreement, of any of the following: (i) the adoption or taking effect of any law, rule, regulation or treaty, (ii) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority or (iii) the making or issuance of any

request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; <u>provided</u> that, notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Closing Date" means the date of the making of the Loans hereunder, which in no event shall be later than January 9, 2020.

"Closing Date Certificate" means a closing date certificate executed and delivered by an Authorized Officer of the Borrower in form and substance reasonably satisfactory to the Administrative Agent.

"CMS" means the U.S. Center for Medicare and Medicaid Services.

"Code" means the Internal Revenue Code of 1986, as amended from time to time.

"Collateral" is defined in the Security Agreement.

"Commitment" means, as to each Lender, such Lender's obligation (if any) to make Loans hereunder.

"Commitment Amount" as to each Lender, means its obligation to make a portion of the Loans to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Commitment Amount of all of the Lenders as in effect on the Closing Date is \$200,000,000.

"Competitor" means any Person that is an operating company engaged in substantially similar business operations as Holdings, Borrower or any of their Subsidiaries.

"Compliance Certificate" means a certificate duly completed and executed by an Authorized Officer of the Borrower, substantially in the form of Exhibit C hereto, together with such changes thereto as the Administrative Agent may from time to time reasonably request for the purpose of monitoring the Borrower's compliance with the financial covenant contained herein.

"Confidential Information" means any and all information or material (whether written or oral, or in electronic or other form) that, at any time before, on or after the Closing Date, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party pursuant to this Agreement or in connection with the transactions contemplated hereby, and shall include the existence and terms of this Agreement.

"Contingent Liability" means any agreement, undertaking or arrangement by which any Person guarantees, endorses or otherwise becomes or is contingently liable upon (by direct or indirect agreement, contingent or otherwise, to provide funds for payment, to supply funds to, or

otherwise to invest in, a debtor, or otherwise to assure a creditor against loss) the Indebtedness of any other Person (other than by endorsements of instruments in the course of collection), or guarantees the payment of dividends or other distributions upon the Capital Securities of any other Person. The amount of any Person's obligation under any Contingent Liability shall (subject to any limitation set forth therein) be deemed to be the outstanding amount of the debt, obligation or other liability guaranteed thereby.

"Control" is defined within the definition of "Affiliate".

"Controlled Account" is defined in Section 7.13.

"Controlled Investment Affiliate" shall mean, with respect to any Person, any other Person that (a) directly or indirectly, is in control of, is controlled by, or is under common control with, such Person, and (b) is organized primarily for the purpose of making equity or debt investments in one or more companies. For purposes of this definition, "control" means the possession, directly or indirectly through one or more intermediaries, of the power to direct the management and policies of a Person, whether through the ownership of Capital Securities, by contract, or otherwise.

"Copyrights" means all copyrights, whether statutory or common law, and all exclusive licenses from third parties or rights to use copyrights owned by such third parties, along with any and all (i) renewals, revisions, extensions, derivative works, enhancements, modifications, updates and new releases thereof, (ii) income, royalties, damages, claims and payments now and hereafter due and/or payable with respect thereto, including, without limitation, damages and payments for past, present or future infringements thereof, (iii) rights to sue for past, present and future infringements thereof, and (iv) foreign copyrights and any other rights corresponding thereto throughout the world.

"Copyright Security Agreement" means any Copyright Security Agreement executed and delivered to the Administrative Agent by Holdings, the Borrower or any of the Subsidiaries in substantially the form of Exhibit C to the Security Agreement, as amended, supplemented, amended and restated or otherwise modified from time to time.

"<u>Debtor Relief Laws</u>" means the Bankruptcy Code of the United States and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief laws of the United States or other applicable jurisdictions from time to time in effect.

"<u>Default</u>" means any Event of Default or any condition, occurrence or event which, after notice or lapse of time or both, would constitute an Event of Default.

"Designated Jurisdiction" means any country or territory to the extent that such country or territory is the subject of any Sanction.

"<u>Designated Key Contracts</u>" means those Key Contracts defined in clauses (a) through (h) of the definition thereof, including any replacements of such Key Contracts.

"Disclosing Party" means the Party disclosing Confidential Information.

"<u>Disposition</u>" (or similar words such as "<u>Dispose</u>") means any sale, transfer, lease, license, contribution or other conveyance (including by way of merger) of, or the granting of options, warrants or other rights to, any of Holdings, the Borrower's or the Subsidiaries' assets (including accounts receivable and Capital Securities of Subsidiaries) to any other Person (other than by Holdings, the Borrower or any of its Subsidiaries) in a single transaction or series of transactions. For the avoidance of doubt, (i) the granting or incurrence of a Lien by Holdings, the Borrower or any Subsidiary on any of its property permitted under <u>Section 8.3</u> or (ii) the making of any Restricted Payment in cash, Capital Securities of Holdings or any combination thereof permitted under <u>Section 8.6</u>, the making of any Restricted Payment by the Borrower or Subsidiaries to Holdings, the Borrower or any Subsidiaries permitted under <u>Section 8.6</u> or the making of any Restricted Payment by Holdings under <u>Section 8.6(b)</u> shall not constitute a "Disposition" for any purpose under this Agreement or under any other Loan Document.

"Disqualified Capital Securities" shall mean any Capital Securities that, by their terms (or by the terms of any security or other Capital Securities into which they are convertible or for which they are exchangeable) or upon the happening of any event or condition, (a) mature or are mandatorily redeemable (other than solely for Qualified Capital Securities), pursuant to a sinking fund obligation or otherwise (except as a result of a Change in Control or asset sale so long as any rights of the holders thereof upon the occurrence of a Change in Control or asset sale event shall be subject to the prior repayment in full of the Loans and all other Obligations that are accrued and payable and the termination of the Commitment), (b) are redeemable at the option of the holder thereof (other than solely for Qualified Capital Securities) (except as a result of a Change in Control or asset sale so long as any rights of the holders thereof upon the occurrence of a Change in Control or asset sale event shall be subject to the prior repayment in full of the Loans and all other Obligations that are accrued and payable and the termination of the Commitment), in whole or in part, (c) provide for the scheduled payment of dividends in cash or (d) are or become convertible into or exchangeable for Indebtedness or any other Capital Securities that would constitute Disqualified Capital Securities, in each case, prior to the date that is one hundred and eighty-one (181) days after the Maturity Date; provided that if such Capital Securities are issued pursuant to a plan for the benefit of employees of Holdings, the Borrower or any of its Subsidiaries, or by any such plan to such employees, such Capital Securities shall not constitute Disqualified Capital Securities solely because they may be required to be repurchased by Holdings, the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations.

"Disqualified Institutions" means any Person that is (a) designated by Borrower, by written notice delivered to Administrative Agent on or prior to the date hereof, as a (i) disqualified institution or (ii) Competitor or (b) clearly identifiable, solely on the basis of such Person's name, as an Affiliate of any Person referred to in clause (a)(i) or (a)(ii) above; provided, however, Disqualified Institutions shall (A) exclude any Person that Borrower has designated as no longer being a Disqualified Institution by written notice delivered to Administrative Agent from time to time and (B) include (I) any Person that is added as a Competitor and (II) any Person that is clearly identifiable, solely on the basis of such Person's name, as an Affiliate of any Person referred to in clause (B)(I), pursuant to a written supplement to the list of Competitors that are Disqualified Institutions, that is delivered by Borrower after the date hereof to Administrative Agent, such supplement shall become effective five (5) Business Days after

the date that such written supplement is delivered to Administrative Agent, but which shall not apply retroactively to disqualify any Persons that have previously acquired an assignment or participation interest in the Loans and/or Commitments as permitted herein. In no event shall a Bona Fide Debt Fund be a Disqualified Institution unless such Bona Fide Debt Fund is identified under clause (a)(i) above.

"<u>Division/ Series Transaction</u>" means, with respect to any Person that is a limited liability company organized under the Laws of the State of Delaware, that any such Person (a) divides into two or more Persons (whether or not the original Person survives such division) or (b) creates, or reorganizes into, one or more series, in each case, as contemplated under the Laws of the State of Delaware.

"EBITDA" shall mean, for any period, with respect Holdings, the Borrower and the Subsidiaries, calculated on a consolidated basis, (a) net income for such period plus (b) without duplication and to the extent deducted in computing such net income for such period (other than in the case of clause (x) below), the sum of (i) interest expense for such period, (ii) the amount of federal, state, local and foreign taxes accrued or paid in cash during such period, (iii) depreciation and amortization expense for such period, (iv) fees and expenses incurred in connection with the negotiation, execution and delivery on the Closing Date of the Investment Documents and the consummation of the transactions contemplated thereby, (v) fees, costs and expenses incurred in connection with any amendments, restatements, supplements, modifications, extensions, consents, waivers, joinders or other changes to this Agreement or any other Investment Documents (in each case, whether or not consummated), (vi) fees, costs and expenses incurred in connection with the consummation of any transaction, or any transaction proposed and not consummated, in each case, that is a financing transaction (including, without limitation, an initial public offering of the Capital Securities of Holdings or the issuances of Capital Securities for financing purposes), acquisition, Disposition or Investment outside the ordinary course of business that is permitted under the Loan Documents (including any amendments, restatements, supplements, modifications, extensions, consents, waivers, joinders of other changes of any documents, agreements or instruments, in each case relating to the foregoing and that are permitted under the Loan Documents), (vii) extraordinary, unusual or non-recurring losses or expenses or legal settlements outside the ordinary course of business (including all fees and expenses relating thereto) in an aggregate amount not to exceed 20% of EBITDA with respect to such period (after giving effect to the addbacks pursuant to this clause (b)(vii)) or as otherwise approved by the Administrative Agent, in its sole discretion, (viii) all non-cash items, expenses or charges reducing net income for such period and (ix) losses, expenses and payments that are covered by insurance, indemnification, reimbursement, guaranty or purchase price adjustment provisions in any document, agreement or instrument entered into by such Persons to the extent such losses, expenses and payments have been (or are reasonably anticipated to be) reimbursed pursuant to the applicable third party insurance, indemnity, guaranty or acquisition agreement in (A) such period, (B) an earlier period if not previously added back to EBITDA in such earlier period or (C) within one year of the date such losses, expenses or payments are incurred; provided that, with respect to this clause (b)(ix), any amounts added back to EBITDA pursuant to clause (b)(ix)(C) in a prior period that was not actually reimbursed or paid to such Persons during such one-year period may not be added back pursuant to this clause (b)(ix) during any later period after such one-year period if such amount is actually reimbursed or paid to such Persons in such later period, minus (c) without duplication and to the

extent included in computing such net income for such period, (i) all non-cash income or gains increasing net income for such period and (ii) extraordinary, unusual or non-recurring income or gains or legal settlements outside the ordinary course of business increasing net income for such period, in each case of clauses (a) through (c) for such Persons on a consolidated basis as determined in accordance with GAAP.

"Eligible Assignee" means any Person that meets the requirements to be an assignee under Section 10.10(b)(iii) and (v) (subject to such consents, if any, as may be required under Section 10.10(b)(iii)).

"EMA" means the European Medicines Agency or any successor entity.

"Environmental Laws" means all federal, state, local or international laws, statutes, rules, regulations, codes, directives, treaties, requirements, ordinances, orders, decrees, judgments, injunctions, notices or binding agreements issued, promulgated or entered into by any Governmental Authority, relating in any way to the environment, natural resources, Hazardous Material or health and safety matters.

"Environmental Liability." means any liability, loss, claim, suit, action, investigation, proceeding, damage, commitment or obligation, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of or affecting Holdings, the Borrower or any Subsidiary directly or indirectly arising from, in connection with or based upon (i) any Environmental Law or Environmental Permit, (ii) the generation, use, handling, transportation, storage, treatment, recycling, presence, disposal, Release or threatened Release of, or exposure to, any Hazardous Materials, or (iii) any contract, agreement, penalty, order, decree, settlement, injunction or other arrangement (including operation of law) pursuant to which liability is assumed, entered into, inherited or imposed with respect to any of the foregoing.

"Environmental Permit" is defined in Section 6.7.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time.

"ERISA Affiliate" means, as applied to any Person, (i) any corporation that is a member of a controlled group of corporations within the meaning of section 414(b) of the Code of which that Person is a member, (ii) any trade or business (whether or not incorporated) that is a member of a group of trades or businesses under common control within the meaning of section 414(c) of the Code of which that Person is a member, or (iii) any member of an affiliated service group within the meaning of section 414(n) or 414(o) of the Code of which that Person, any corporation described in clause (i) above or any trade or business described in clause (ii) above is a member.

"Event of Default" is defined in Section 9.1.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Excluded Account" is defined in Section 7.13.

"Existing Debt Refinancing" is defined in Section 5.4.

"Exit Fee" is defined in Section 3.8.

"FATCA" means Sections 1471 through 1474 of the Code, as of the Closing Date (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any applicable agreements entered into pursuant to Section 1471(b)(1) of the Code, any applicable intergovernmental agreements with respect to the implementation of Sections 1471 through 1474 of the Code, and any fiscal or regulatory legislation, rules or official administrative practices adopted pursuant to any such intergovernmental agreement, or treaty or convention among Governmental Authorities, and implementing such Sections of the Code.

"FDA" means the U.S. Food and Drug Administration and any successor entity.

"FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act (or any successor thereto), as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Federal Funds Rate" means, for any day, the rate per annum equal to the weighted average of the rates on overnight federal funds transactions with members of the Federal Reserve System arranged by federal funds brokers on such day, as published by the Federal Reserve Bank of New York on the Business Day next succeeding such day; provided that if such day is not a Business Day, the Federal Funds Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day.

"Fiscal Quarter" means a quarter ending on the last day of March, June, September or December.

"<u>Fiscal Year</u>" means any period of twelve consecutive calendar months ending on December 31; references to a Fiscal Year with a number corresponding to any calendar year (<u>e.g.</u>, the "2019 Fiscal Year") refer to the Fiscal Year ending on December 31 of such calendar year.

"Foreign Lender" means a Lender that is not organized under the laws of the United States (excluding territories and possessions), any state thereof, or the District of Columbia.

"Foreign Subsidiary" means a Subsidiary of Borrower that is not organized under the laws of the United States, any state thereof, or the District of Columbia.

"F.R.S. Board" means the Board of Governors of the Federal Reserve System or any successor thereto.

"FTC Act" means the Federal Trade Commission Act.

"<u>Fund</u>" means any Person (other than a natural Person) that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its activities.

"GAAP" means generally accepted accounting principles in the United States.

"Governmental Authority" means any national, supranational, federal, state, county, provincial, local, municipal or other government or political subdivision thereof (including any Regulatory Agency), whether domestic or foreign, and any agency, authority, commission, ministry, instrumentality, regulatory body, court, tribunal, arbitrator, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to any such government.

"<u>Guarantee</u>" means the guarantee executed and delivered by an Authorized Officer of each Subsidiary, substantially in the form of <u>Exhibit D</u> hereto, as amended, supplemented, amended and restated or otherwise modified from time to time.

"Guarantors" means, collectively, Holdings and the Subsidiaries.

"Hazardous Material" means any material, substance, chemical, mixture or waste which is capable of damaging or causing harm to any living organism, the environment or natural resources, including all explosive, special, hazardous, polluting, toxic, industrial, dangerous, biohazardous, medical, infectious or radioactive substances, materials or wastes, noise, odor, electricity or heat, and including petroleum or petroleum products, byproducts or distillates, asbestos or asbestos-containing materials, urea formaldehyde, polychlorinated biphenyls, radon gas, ozone-depleting substances, greenhouse gases, and all other substances or wastes of any nature regulated pursuant to any Environmental Law or as to which any Governmental Authority requires investigation, reporting or remedial action.

"<u>Hedging Obligations</u>" means, with respect to any Person, all liabilities of such Person under currency exchange agreements, interest rate swap agreements, interest rate cap agreements and interest rate collar agreements, and all other agreements or arrangements designed to protect such Person against fluctuations in interest rates or currency exchange rates.

"herein", "hereof", "hereto", "hereunder" and similar terms contained in any Loan Document refer to such Loan Document as a whole and not to any particular Section, paragraph or provision of such Loan Document.

"Holdings" means Harmony Biosciences II, Inc., a Delaware corporation.

"Impermissible Qualification" means any qualification or exception to the opinion or certification of any independent public accountant as to any financial statement of Holdings, the Borrower or any Subsidiary (i) which is of a "going concern" or similar nature (except as may be required as a result of the impending maturity of any Indebtedness, including the Loans and Obligations under the Loan Documents) (ii) which relates to the limited scope of examination of matters relevant to such financial statement, or (iii) which relates to the treatment or classification of any item in such financial statement and which, as a condition to its removal, would require an adjustment to such item the effect of which would be to cause the Borrower to be in Default.

"including" and "include" means including without limiting the generality of any description preceding such term, and, for purposes of each Loan Document, the parties hereto agree that the rule of ejusdem generis shall not be applicable to limit a general statement, which is followed by or referable to an enumeration of specific matters, to matters similar to the matters specifically mentioned.

"Indebtedness" of any Person means:

- (a) all obligations of such Person for borrowed money or advances and all obligations of such Person evidenced by bonds, debentures, notes or similar instruments;
- (b) all obligations, contingent or otherwise, relative to the face amount of all letters of credit, whether or not drawn, and banker's acceptances issued for the account of such Person;
 - (c) all Capitalized Lease Liabilities of such Person and all obligations of such Person arising under Synthetic Leases;
- (d) net Hedging Obligations of such Person; <u>provided</u> that the amount of any net Hedging Obligation on any date shall be deemed to be the Swap Termination Value thereof as of such date;
 - (e) all obligations of such Person in respect of Disqualified Capital Securities;
- (f) whether or not so included as liabilities in accordance with GAAP, all obligations of such Person to pay the deferred purchase price of property or services (excluding (i) trade accounts payable in the ordinary course of business which are not overdue for a period of more than 90 days or, if overdue for more than 90 days, as to which a dispute exists and adequate reserves in conformity with GAAP have been established on the books of such Person, (ii) accruals for payroll and other similar employee liabilities accrued in the ordinary course of business and (iii) royalty or milestone payments not yet due and payable (and not paid when due)), in the case of earnouts or any other similar contingent obligations, to the extent due and payable but not yet paid if the same would be required to be shown as a liability on the balance sheet prepared in accordance with GAAP;
- (g) Indebtedness secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) a Lien on property owned or being acquired by such Person (including Indebtedness arising under conditional sales or other title retention agreements), whether or not such Indebtedness shall have been assumed by such Person or is limited in recourse; provided that the amount of any non-recourse Indebtedness shall be limited to the fair market value of any property securing such Indebtedness if less than the aggregate outstanding amount of such Indebtedness; and
 - (h) all Contingent Liabilities of such Person in respect of any of the foregoing.

The Indebtedness of any Person shall include the Indebtedness of any other Person (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such Person,

except to the extent the terms of such Indebtedness provide that such Person is not liable therefor. Notwithstanding anything to the contrary contained herein, Indebtedness shall not include obligations in respect of customary retention or stay bonuses and severance arrangements.

"Indemnified Liabilities" is defined in Section 10.4.

"Indemnified Parties" is defined in Section 10.4.

"Infringement" and "Infringes" mean the misappropriation or other violation of any Intellectual Property.

"Intellectual Property" means all (i) Patents and all patent applications of any type, registrations and renewals, reissues, reexaminations and patent rights in any lawful form thereof; (ii) Trademarks and all applications, registrations and renewals thereof; (iii) Copyrights and other works of authorship (registered or unregistered), and all applications, registrations and renewals therefor; (iv) computer software, databases, data and documentation; (v) trade secrets and confidential business information, whether patentable or unpatentable and whether or not reduced to practice, know-how, inventions, manufacturing processes and techniques, research and development information, data and other information, including any such information included in or supporting Key Permits; (vi) proprietary financial, marketing and business data, pricing and cost information, business, finance and marketing plans, customer and prospective customer lists and information, and supplier and prospective supplier lists and information; (vii) other intellectual property or similar proprietary rights; (viii) copies and tangible embodiments of any of the foregoing (in whatever form or medium); and (ix) any and all improvements, developments, refinements, additions or subtractions to any of the foregoing.

"Interest Period" means, (a) initially, the period beginning on (and including) the date on which the Loans are made hereunder pursuant to Section 2.3 and ending on (and including) the last day of the month in which the Loans were made, and (b) thereafter, the period beginning on (and including) the first day of each succeeding month and ending on the earlier of (and including) (x) the last day of such month and (y) the Maturity Date.

"Investment" means, relative to any Person, (i) any loan, advance or extension of credit made by such Person to any other Person, including the purchase by such Person of any bonds, notes, debentures or other debt securities of any other Person, (ii) Contingent Liabilities in favor of any other Person, and (iii) any Capital Securities held by such Person in any other Person. The amount of any Investment shall be the original principal or capital amount thereof less all returns of principal or equity thereon and shall, if made by the transfer or exchange of property other than cash, be deemed to have been made in an original principal or capital amount equal to the fair market value of such property at the time of such Investment. For the avoidance of doubt, the granting or incurrence of a Lien by any Person in favor of any other Person shall not constitute an "Investment" for any purpose hereunder or under any other Loan Document.

"Investment Documents" means, collectively, the Loan Documents and the Lender Warrants.

"Key Contracts" means (a) the License Agreement, (b) that certain Trademark License Agreement, dated as of August 2018, among Bioprojet Europe, Ltd., Bioprojet Société Civile de Recherche and the Borrower, (c) that certain Contract Manufacturing Agreement, dated as of December 19, 2019, by and between the Borrower and Corden Pharma Chenove SAS (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment), (d) that certain Packaging Agreement, dated as of December 3, 2018, by and between the Borrower and Carton Service, Inc. (d.b.a Pharma Packaging Solutions) (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment), (e) that certain Commercial Outsourcing Services Agreement, dated as of February 8, 2019, by and between the Borrower and Integrated Commercialization Solutions, LLC (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment), (f) that certain Contract Manufacturing Agreement, dated as of April 5, 2019, by and between the Borrower and Interor SA (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment), (g) that certain Manufacturing Services Agreement, dated as of March 13, 2018, by and between Patheon UK Limited and Bioprojet Pharma SAS (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment), (h) that certain Deed of Novation, dated as of January 31, 2019, by and among Patheon UK Limited, Bioprojet Pharma SAS and the Borrower (as may be terminated and, in connection with such termination, replaced from time to time by Borrower or its Subsidiaries in their reasonable business judgment) and (i) any other agreement between Bioprojet Société Civile de Recherche, Bioprojet Pharma SAS or Bioprojet Europe, Ltd. or any of their Affiliates, on the one hand, and Holdings, the Borrower or any Subsidiary, on the other hand, the absence of, or breach or default under, which would reasonably be expected to result in a material adverse consequence under any Designated Key Contract (excluding any agreements (including investment agreements) to which Bioprojet Société Civile de Recherche, Bioprojet Pharma SAS or Bioprojet Europe, Ltd. or any of their Affiliates is a party with Holdings, the Borrower and/or one or more of its direct or indirect shareholders, solely in their respective capacities as holders of the Capital Securities of Holdings, including, without limitation, agreements with respect to the issuances thereof), in each case as amended, supplemented or otherwise modified from time to time. For the avoidance of doubt, any replacement of a Designated Key Contract listed in this definition shall be a Key Contract.

"Key Permits" means all Permits relating to the Products, including all Regulatory Authorizations.

"knowledge" of the Borrower means the knowledge of, so long as he or she is employed by Borrower, the Chief Executive Officer, the Chief Financial Officer, the Chief Business Officer, Chief Medical Officer or General Counsel of Borrower.

"<u>LatAm Transaction</u>" means the transactions described on <u>Schedule 1</u>; <u>provided</u> that the total cash and non-cash consideration paid or payable by or on behalf of Holdings, the Borrower and its Subsidiaries (including any milestone payments not yet due and payable, but excluding any royalty payments to the extent based on net sales of products) for such transaction shall not exceed an aggregate cumulative amount of \$5,000,000.

"<u>LatAm Transaction Documents</u>" means any license, agreement, instrument or other document entered into by Holdings, the Borrower or any Subsidiary in connection with the LatAm Transaction.

"<u>Laws</u>" means all applicable U.S. federal, state, local or foreign laws, statutes, ordinances, rules, regulations, guidances, judgments, orders, injunctions, decrees, arbitration awards and Key Permits issued by any Governmental Authority, including Privacy Laws.

"Lender" means each Person identified as a "Lender" on the signature pages hereto and its successors and permitted assigns.

"<u>Lender Warrants</u>" means those certain warrants to purchase Shares issued to the Lenders on the Closing Date and substantially in the form of <u>Exhibit G</u>.

"LIBO Rate" means the one-month London Interbank Offered Rate for deposits in U.S. Dollars at approximately 11:00 a.m. (London, England time), quoted by the Administrative Agent from the appropriate Bloomberg or Telerate page selected by the Administrative Agent (or any successor thereto or similar source determined by the Administrative Agent from time to time), which shall be that one-month London Interbank Offered Rate for deposits in U.S. Dollars in effect two Business Days prior to the first Business Day of the relevant calendar month, adjusted for any reserve requirement and any subsequent costs arising from a change in governmental regulation, such rate to be rounded up to the nearest 1/16 of 1% and such rate to be reset monthly as of the first Business Day of each calendar month; provided that if the LIBO Rate shall be less than 2.00%, such rate shall be deemed to be 2.00% for the purposes of this Agreement. If the Loans are advanced other than on the first Business Day of a calendar month, the initial LIBO Rate shall be that one-month London Interbank Offered Rate for deposits in U.S. Dollars in effect two Business Days prior to the date of the Loans, which rate shall be in effect until (and including) the last Business Day of the calendar month next ending. The Administrative Agent's internal records of applicable interest rates shall be determinative in the absence of manifest error.

"License Agreement" means that certain License and Commercialization Agreement, dated as of July 27, 2018, between Bioprojet and the Borrower, (a) as amended by that certain Amendment No. 1 to License and Commercialization Agreement, dated as of August 27, 2018, (b) as modified by that certain Limited Waiver of License and Commercialization Agreement, dated as of March 27, 2019 (as amended by (i) that certain Amendment to Limited Waiver of License and Commercialization Agreement, dated as of April 5, 2019 and (ii) that Second Amendment to Limited Waiver of License and Commercialization Agreement, dated as of April 9, 2019) and (c) as may be further amended, supplemented, amended and restated or otherwise modified from time to time after the date hereof in accordance with the terms thereof and hereof.

"<u>Licensed Intellectual Property</u>" means all Intellectual Property that is not Owned Intellectual Property, which is licensed to, or otherwise used or held for use, by Holdings, the Borrower or any Subsidiary.

"<u>Lien</u>" means any security interest, mortgage, pledge, hypothecation, collateral assignment, deposit arrangement, encumbrance, lien (statutory or otherwise), charge against or interest in property, or other priority or preferential arrangement of any kind or nature whatsoever, to secure payment of a debt or performance of an obligation.

"<u>Liquidity</u>" means, at any time, an amount determined for Holdings, the Borrower and the Subsidiaries equal to the sum of unrestricted cash-on-hand and Cash Equivalent Investments of Holdings, the Borrower and such Subsidiaries, to the extent held in a Controlled Account located in the United States.

"Loans" is defined in Section 2.1.

"Loan Documents" means, collectively, this Agreement, the Notes, the Security Agreement, each other agreement pursuant to which the Secured Parties are granted a Lien to secure the Obligations (including any mortgages entered into pursuant to Section 7.8), the Guarantee, and each other agreement, certificate, document or instrument delivered in connection with any Loan Document, whether or not specifically mentioned herein or therein.

"Loan Request" means a Loan request and certificate duly executed by an Authorized Officer of the Borrower substantially in the form of Exhibit B hereto.

"Material Adverse Effect" means a material adverse effect on (i) the business, financial condition, operations, performance or properties of the Borrower or of Holdings, the Borrower and the Subsidiaries taken as a whole, (ii) the rights and remedies (taken as a whole) of any Secured Party under any Loan Document or (iii) the ability of Holdings, the Borrower and the Subsidiaries, taken as a whole, to perform their Obligations under any Loan Document.

"Material Agreements" means (i) each contract or agreement to which Holdings, the Borrower or any Subsidiary is a party involving aggregate payments of more than \$1,000,000 per Fiscal Year, whether such payments are being made by Holdings, the Borrower or any Subsidiary to a non-Affiliated Person, or by a non-Affiliated Person to Holdings, the Borrower or any Subsidiary (excluding, in all cases, any contract or agreement solely among one or more of Holdings and its Subsidiaries); and (ii) all other contracts or agreements entered into by Holdings, the Borrower or any Subsidiary, the absence or termination of which would reasonably be expected to have a Material Adverse Effect, including, for the avoidance of doubt, the LatAm Transaction Documents; provided, however, that "Material Agreements" excludes all (i) licenses implied by the sale of a product and (ii) paid-up licenses for commonly available software programs under which Holdings, the Borrower or a Subsidiary is the licensee.

"Maturity Date" means January 9, 2026.

"Moody's" means Moody's Investors Service, Inc.

"Net Asset Sales Proceeds" means, with respect to a Disposition (other than Dispositions permitted by Sections 8.8(a) - (k) and (m) - (n) after the Closing Date by Holdings, the Borrower or any Subsidiary to any Person of any assets of Holdings, the Borrower or any Subsidiary, the excess of gross cash proceeds received by Holdings, the Borrower or any Subsidiary from such Disposition, other than proceeds that are, or will be, (a) reinvested within 180 days of receipt of such proceeds in similar assets of a kind that are then used or useful in the conduct of the business of Holdings or any of its Subsidiaries (or, to the extent that Holdings,

Borrower or any Subsidiary enters into a binding commitment thereof within said one hundred eighty (180) day period and subsequently makes such reinvestment within an additional one hundred eighty (180) days thereafter, such proceeds that are, or will be, so reinvested) or (b) required to be paid to a creditor (other than to the Lenders) which holds a first priority Lien securing Indebtedness permitted by Section 8.2(e) or (j) on the property which is the subject of such Disposition, over all reasonable and customary costs and expenses, and including Taxes paid or payable or required to be paid or payable by the recipient of such proceeds, incurred in connection with such Disposition which have not been paid to Affiliates of the Borrower in connection therewith, in excess of \$500,000 in the aggregate.

"Net Casualty Proceeds" means, with respect to any Casualty Event, any insurance proceeds or condemnation awards received by Holdings, the Borrower, or any Subsidiary in connection with such Casualty Event, other than proceeds that are, or will be, (a) reinvested within 180 days of receipt of such proceeds in similar assets of a kind that are then used or useful in the conduct of the business of Holdings or any of its Subsidiaries (or, to the extent that Holdings, the Borrower or any Subsidiary enters into a binding commitment thereof within said one hundred eighty (180) day period and subsequently makes such reinvestment within an additional one hundred eighty (180) days thereafter, such proceeds that are, or will be, so reinvested) or (b) required to be paid to a creditor (other than to the Lenders) which holds a first priority Lien securing Indebtedness permitted by Section 8.2(e) or (j) on the property which is the subject of such Casualty Event, over all reasonable and customary costs and expenses, and including Taxes paid or payable or required to be paid or payable by the recipient of such proceeds, incurred in connection with the receipt of such proceeds which have not been paid to Affiliates of the Borrower in connection therewith, in excess of \$500,000 in the aggregate.

"Net Revenue" means, with respect to any period and any Product, net revenue of Holdings, the Borrower, and its Subsidiaries on account of sales of such Product for such period in the United States, as determined in accordance with GAAP. Net Revenue shall not include any royalty payments, milestone payments, distribution income, service payments, license income, and other similar forms of consideration received by Holdings, the Borrower, and its Subsidiaries. Net Revenue shall be determined in a manner consistent with the methodologies, practices and procedures used in developing Holdings and the Borrower's audited financial statements.

"Non-Excluded Taxes" means any Taxes imposed on or with respect to any payment made by or on account of any obligation of the Borrower under any Loan Document, other than (a) Taxes imposed on or measured by a Person's net income, and franchise Taxes, in both cases with respect to any Lender or the Administrative Agent and that are (x) imposed by any Governmental Authority under the laws of which such Lender or the Administrative Agent is organized or in which it maintains its applicable lending office, or (y) imposed as a result of a present or former connection between such Lender or the Administrative Agent and the jurisdiction imposing such Tax (other than connections solely arising from such Lender or Administrative Agent having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document), (b) branch profits taxes imposed by the United States or any similar tax imposed by any other jurisdiction described in paragraph (a) above, and (c) (i) any

withholding tax that is imposed by the United States on amounts payable to a Lender at the time such Lender first becomes a party to this Agreement (or designates a new lending office), except to the extent that such Lender (or its assignor, if any) was entitled, at the time of designation of a new lending office (or assignment), to receive additional amounts from the Borrower with respect to such withholding tax pursuant to Section 4.3(a), (ii) Taxes attributable to such Lender's or Administrative Agent's failure to comply with Section 2.19(g), or (iii) any withholding Taxes or other amounts imposed or payable under FATCA.

"Note" means a promissory note of the Borrower payable to a Lender, in the form of Exhibit A hereto (as such promissory note may be amended, endorsed or otherwise modified from time to time), evidencing the aggregate Indebtedness of the Borrower to such Lender resulting from the outstanding amount of the Loans, and also means all other promissory notes accepted from time to time in substitution therefor or renewal thereof.

"Obligations" means all obligations (monetary or otherwise, whether absolute or contingent, matured or unmatured) of Holdings, the Borrower and each Subsidiary arising under or in connection with a Loan Document and the principal of and premium, if any, and interest (including interest accruing during the pendency of any proceeding of the type described in Section 9.1(h), whether or not allowed in such proceeding) on the Loans.

"Observer" is defined in Section 7.14.

"OFAC" means the Office of Foreign Assets Control of the United States Department of the Treasury.

"Organic Document" means, relative to Holdings, the Borrower or any Subsidiary, its certificate of incorporation, by-laws, certificate of partnership, partnership agreement, certificate of formation, limited liability agreement, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to Holdings', the Borrower's or any Subsidiary's Capital Securities.

"Other Administrative Proceeding" means any administrative proceeding relating to a dispute involving a patent office or other relevant intellectual property registry which relates to validity, opposition, revocation, ownership or enforceability of the relevant Intellectual Property.

"Other Taxes" means any and all stamp, court or documentary, intangible, recording, filing or similar Taxes that arise on account of any payment made or required to be made under any Loan Document or from the execution, delivery, registration, recording or enforcement of any Loan Document (excluding, for the avoidance of doubt, Taxes described in clauses (a), (b) or (c) of the definition of Non-Excluded Taxes, and any such Taxes imposed with respect to an assignment (other than an assignment at the request of the Borrower).

"Owned Intellectual Property" means all Intellectual Property that is owned or purported to be owned (solely or jointly with others) by Holdings, the Borrower or any Subsidiary.

"Paragon" means Paragon Biosciences, LLC, a Delaware limited liability company.

"Paragon Investors" means (a) Marshman Fund Trust I U/A/D 5/1/08, (b) Marshman Fund Trust II U/A/D 5/1/08 or (c) any Controlled Investment Affiliate of any of the foregoing.

"<u>Paragon Management Agreements</u>" means that certain (a) Management Services Agreement, dated as of September 22, 2017, by and among Paragon, Borrower and, solely with respect to Section 6 therein, Jeffrey S. Aronin and (b) Right of Use Agreement, dated as of November 1, 2019, by and between Paragon and Borrower, in each case, as amended, supplemented, amended and restated or otherwise modified from time to time after the date hereof in accordance with the terms thereof and hereof.

"Party" and "Parties" have the meanings set forth in the preamble hereto.

"Patent" means any patent, any type of patent application or invention disclosure, including all divisions, continuations, continuations in-part, provisionals, continued prosecution applications, substitutions, reissues, reexaminations, inter partes review, post-grant review by any Governmental Authority, renewals, extensions, adjustments, restorations, supplemental protection certificates and patent rights in any form and other additions in connection therewith, whether in or related to the United States or any foreign country or other jurisdiction.

"<u>Patent Security Agreement</u>" means any Patent Security Agreement executed and delivered to the Administrative Agent by Holdings, the Borrower or any of the Subsidiaries in substantially the form of Exhibit A to the Security Agreement, as amended, supplemented, amended and restated or otherwise modified from time to time.

"Permits" means all permits, licenses, registrations, certificates, orders, approvals, authorizations, consents, clearances, waivers, franchises, variances and similar rights issued by or obtained from any Governmental Authority or any other Person, including, without limitation, those relating to Environmental Laws and Regulatory Authorizations.

"<u>Permitted Acquisition</u>" means the purchase or other acquisition of all of the Capital Securities (other than qualifying directors' shares) in, or all or substantially all of the property of any Person (or any division, business unit or line of business thereof, including any geographic subset thereof, other than any joint venture owned by another Person that is purchased or acquired), including through an exclusive lease or license (such purchase or acquisition, an "<u>Acquisition</u>"), that, upon the consummation thereof, will be wholly owned directly by the Borrower or one or more of its wholly owned Subsidiaries (including as a result of a merger or consolidation); <u>provided</u> that, with respect to each Permitted Acquisition:

- (a) any such newly-created or acquired Subsidiary shall comply with the requirements of <u>Section 7.8</u> and the Secured Parties shall have received (or shall receive in connection with the closing of such acquisition) a first priority perfected security interest, subject only to Liens permitted under <u>Section 8.3</u>, in the property (including, without limitation, Capital Securities) acquired with respect to the entity acquired;
- (b) the lines of business of the Person to be (or the property of which is to be) so purchased or otherwise acquired shall be permitted pursuant to Section 8.1;

- (c) in the case of a purchase or other acquisition of the Capital Securities of another Person, the board of directors (or other comparable governing body) of such other Person shall have duly approved such purchase or other acquisition;
- (d) the total cash and non-cash consideration paid by or on behalf of Holdings, the Borrower and its Subsidiaries for any such purchase or other acquisition, when aggregated with the consideration paid by or on behalf of Holdings, the Borrower and its Subsidiaries for all other Permitted Acquisitions after the Closing Date shall not exceed the aggregate amount of \$3,000,000 in any Fiscal Year and an aggregate cumulative amount of \$5,000,000; provided that, such calculation of total cash and non-cash consideration for any Permitted Acquisition shall exclude any consideration (x) to the extent financed with the issuance of Qualified Capital Securities issued on or up to sixty (60) days prior to the date of consummation of such transaction and not used to consummate Investments permitted under Section 8.5(1) so long as EBITDA, calculated both before, and on a pro forma basis after, giving effect to such purchase or other acquisition, is no less than \$10,000,000 or (y) paid in connection with the LatAm Transaction.
- (e) immediately before and after giving effect to any such purchase or other acquisition, no Default or Event of Default, shall exist or result therefrom; and
- (f) the Borrower shall have delivered to the Administrative Agent and the Lenders, at least seven (7) Business Days prior to the date on which any such purchase or other acquisition is to be consummated (or such later date as may be agreed to by the Administrative Agent), a written notice describing such transaction, and thereafter, if requested by any Lender for any such transaction involving consideration in excess of \$500,000, (i) to the extent available, historical financial statements of or related to the Person or assets to be acquired, (ii) twelve month projections for such Person or assets to be acquired and for the Borrower after giving effect to such transaction, and (iii) material documentation and other information relating to such transaction and reasonably requested by any Lender.

"Permitted Refinancing" means, with respect to any Indebtedness, any extensions, renewals, refinancings and replacements of such Indebtedness; provided that such extension, renewal, refinancing or replacement (a) shall not increase the outstanding principal amount of such Indebtedness, except by an amount equal to unpaid accrued interest and premium (including tender premiums) thereon plus other reasonable amounts paid (including original issue discount and upfront fees), and fees and expenses reasonably incurred, in connection with such renewals, refinancing or replacement and by an amount equal to any existing commitments unutilized thereunder, (b) contains terms relating to outstanding principal amount, amortization, maturity, collateral (if any) and subordination (if any) taken as a whole no less favorable in any material respect to Holdings and its Subsidiaries or the Secured Parties than such terms of any agreement or instrument governing such existing Indebtedness, (c) shall have an applicable interest rate which does not exceed a market rate of interest at the time such Indebtedness is replaced and (d) shall not contain any new requirement to grant any lien or security or to give any guarantee that was not an existing requirement of such Indebtedness, except with respect to any new Subsidiary or assets acquired on or after the date such Indebtedness is incurred that is also Collateral under the Loan Documents.

"Permitted Subordinated Indebtedness" means Indebtedness incurred after the Closing Date by Holdings, the Borrower or the Subsidiaries that is (i) subordinated to the Obligations and all other Indebtedness owing from Holdings, the Borrower or the Subsidiaries to the Secured Parties pursuant to a written subordination agreement satisfactory to the Administrative Agent in its sole discretion and (ii) in an amount and on terms approved by the Administrative Agent in its sole discretion.

"<u>Person</u>" means any natural person, corporation, limited liability company, partnership, joint venture, association, trust or unincorporated organization, Governmental Authority or any other legal entity, whether acting in an individual, fiduciary or other capacity.

"PHSA" means the Public Health Service Act (or any successor thereto), as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Prime Rate" means (a) the rate of interest last quoted by *The Wall Street Journal* as the "Prime Rate" in the U.S. or, if *The Wall Street Journal* ceases to quote such rate, the per annum interest rate published by the Federal Reserve Board in Federal Reserve Statistical Release H.15 (519) (Selected Interest Rates) as the "bank prime loan" rate or, if such rate is no longer quoted therein, any similar rate quoted therein (as determined by the Administrative Agent) or any similar release by the Federal Reserve Board (as determined by the Administrative Agent), minus (b) 1.00%; provided that if the Prime Rate shall be less than 2.00%, such rate shall be deemed to be 2.00% for the purposes of this Agreement.

"Privacy Laws" means all applicable security and privacy standards regarding protected health information under (i) the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, including the regulations promulgated thereunder (collectively "HIPAA") and (ii) any applicable state privacy Laws.

"Product" means (i) Wakix and (ii) any current or future service or product researched, designed, developed, manufactured, licensed, marketed, sold, performed, distributed or otherwise commercialized by the Borrower or any of its Affiliates, including any such product in development or which may be developed.

"Product Agreement" means each agreement, license, document, instrument, interest (equity or otherwise) or the like under which one or more parties grants or receives any right, title or interest with respect to any Product Development and Commercialization Activities in respect of one or more Products specified therein or to exclude third parties from engaging in, or otherwise restricting any right, title or interest as to any Product Development and Commercialization Activities with respect thereto, including each contract or agreement with suppliers (including human tissue supply agreements), manufacturers, pharmaceutical companies, distributors, clinical research organizations, hospitals, group purchasing organizations, wholesalers, pharmacies or any other Person related to any such entity.

"Product Authorizations" means any and all approvals, licenses, notifications, registrations, clearances or authorizations or other Permits of any Governmental Authority

necessary for the testing, manufacture, development, distribution, use, storage, import, export, transport, promotion, marketing, sale or other commercialization of a Product in any country or jurisdiction, including without limitation registration and listing, INDs, New Drug Applications (including the Wakix NDA or any other New Drug Application directed to pitolisant hydrochloride and any moeity thereof), any related orphan drug exclusivity designation and approval (including the Wakix ODE), any related new chemical entity designation and approval (including the Wakix NCE), and similar applications.

"Product Development and Commercialization Activities" means, with respect to any Product, any combination of research, development, manufacture, import, use, sale, importation, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to commercially exploit such Product.

"<u>Purchase Money Indebtedness</u>" means Indebtedness (1) consisting of the deferred purchase price for equipment incurred in connection with the acquisition of such equipment, where the amount of such Indebtedness does not exceed the greater of (a) the cost of the equipment being financed and (b) the fair market value of such equipment; and (2) incurred to finance such acquisition by Holdings, the Borrower or a Subsidiary of such equipment.

"Qualified Capital Securities" shall mean any Capital Securities that are not Disqualified Capital Securities.

"Qualified IPO" means an underwritten initial public offering of the Capital Securities of Holdings which generates cash proceeds of at least \$75,000,000 and results in a listing of such entity's Capital Securities on a public securities exchange.

"Receiving Party" means the Party receiving Confidential Information.

"Recipient" is defined in Section 10.14.

"Regulatory Agencies" means any Governmental Authority that is concerned with the use, control, safety, efficacy, reliability, manufacturing, testing, marketing, distribution, sale or other Product Development and Commercialization Activities relating to any Product of Holdings, the Borrower or any of the Subsidiaries, including CMS, FDA, and all similar agencies in other jurisdictions, and includes Standard Bodies.

"Regulatory Authorizations" means all approvals, clearances, notifications, authorizations, orders, exemptions, registrations, listings, certifications, licenses and Permits granted by, submitted to or filed with any Regulatory Agencies, including all Product Authorizations.

"Related Parties" means the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of Holdings, the Borrower and the Subsidiaries.

"Release" means any releasing, disposing, discharging, injecting, spilling, leaking, leaching, pumping, pouring, dumping, depositing, emitting, escaping, emptying, seeping, dispersal, migrating or placing, including movement through, into or upon the environment or any natural or man-made structure.

"Repayment Premium" means a premium of

- (a) eight percent (8.0%) of the principal amount of any prepayment or repayment of the Borrower on the Loans, if such prepayment or repayment is made or required to be made on or prior to the 12-month anniversary of the Closing Date;
- (b) four percent (4.0%) of the principal amount of any prepayment or repayment of the Borrower on the Loans, if such prepayment or repayment is not made or required to be made prior to, and is made or required to be made after, the 12-month anniversary of the Closing Date, but on or prior to the 24-month anniversary of the Closing Date;
- (c) two percent (2.0%) of the principal amount of any prepayment or repayment of the Borrower on the Loans, if such prepayment or repayment is not made or required to be made prior to, and is made or required to be made after, the 24-month anniversary of the Closing Date, but on or prior to the 36-month anniversary of the Closing Date; or
- (d) zero percent (0%) of the principal amount of any prepayment or repayment of the Borrower on the Loans, if such prepayment or repayment is not made or required to be made on or prior to, and is made or required to be made after, the 36- month anniversary of the Closing Date.

"Required Lenders" means Lenders having Total Credit Exposures representing more than 50% of the Total Credit Exposures of all Lenders.

"Restricted Payment" means (i) the declaration or payment of any dividend on, or the making of any payment or distribution on account of, or setting apart assets for a sinking or other analogous fund for the purchase, redemption, defeasance, retirement or other acquisition of, any class of Capital Securities of Holdings, the Borrower or any Subsidiary or any warrants, options or other right or obligation to purchase or acquire any such Capital Securities, whether now or hereafter outstanding, (ii) the making of any other distribution in respect of such Capital Securities, in each case either directly or indirectly, whether in cash, property or obligations of Holdings, the Borrower or any Subsidiary or otherwise or (iii) the payment of any management fees, transaction fees, expense reimbursement or other indemnities to any holder of the Capital Securities of Holdings, the Borrower or any Subsidiary or any warrants, options or other right or obligation to purchase or acquire any such Capital Securities in respect of such Capital Securities or in respect of management, sponsoring, structuring, arranging or other services, other than any customary compensation and indemnification of, and other employment arrangement with, directors, officers and employees of Holdings or any of its Subsidiaries in the ordinary course of business.

"S&P" means Standard & Poor's Rating Services, a division of The McGraw-Hill Companies, Inc.

"Sanctions" means any international economic sanction administered or enforced by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority.

"SEC" means the Securities and Exchange Commission.

"Secured Parties" means the Lenders and the Administrative Agent.

"Security Agreement" means the Pledge and Security Agreement executed and delivered by each of the parties thereto, substantially in the form of Exhibit E hereto, as amended, supplemented, amended and restated or otherwise modified from time to time.

"Solvent" means, with respect to any Person on a particular date, that on such date (i) the fair value of the property of such Person is greater than the total amount of liabilities, including contingent liabilities, of such Person, (ii) the present fair saleable value of the assets of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (iii) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond its ability to pay as such debts and liabilities mature, (iv) such Person is not engaged in a business or a transaction, and is not about to engage in a business or a transaction, for which the property of such Person would constitute an unreasonably small capital and (v) such Person has not executed this Agreement or any other Loan Document, or made any transfer or incurred any obligations hereunder or thereunder, with actual intent to hinder, delay or defraud either present or future creditors. The amount of Contingent Liabilities at any time shall be computed as the amount that, in light of all the facts and circumstances existing at such time, can reasonably be expected to become an actual or matured liability.

"Standard Bodies" means any of the organizations that create, sponsor or maintain safety, quality or other standards for any Product, including ISO, ANSI, CEN and SCC and the like.

"Subsidiary" means, with respect to any Person, any other Person of which more than 50% of the outstanding Voting Securities of such other Person (irrespective of whether at the time Capital Securities of any other class or classes of such other Person shall or might have voting power upon the occurrence of any contingency) is at the time directly or indirectly owned or controlled by such Person, by such Person and one or more other Subsidiaries of such Person. Unless the context otherwise specifically requires, the term "Subsidiary" shall be a reference to a Subsidiary of Borrower.

"Swap Termination Value" means, in respect of any one or more Hedging Agreements, after taking into account the effect of any legally enforceable netting agreement relating to such Hedging Agreements, (a) for any date on or after the date such Hedging Agreement has been closed out and termination value(s) determined in accordance therewith, such termination value(s), and (b) for any date prior to the date referenced in clause (a), the amount(s) determined as the mark-to-market value(s) for such Hedging Agreement, as determined based upon one or more mid-market or other readily available quotations provided by any recognized dealer in such Hedging Agreements.

"Synthetic Lease" means, as applied to any Person, any lease (including leases that may be terminated by the lessee at any time) of any property (whether real, personal or mixed) (i) that is not a capital lease in accordance with GAAP and (ii) in respect of which the lessee retains or obtains ownership of the property so leased for federal income tax purposes, other than any such lease under which that Person is the lessor.

"<u>Taxes</u>" means all income, stamp or other taxes, duties, levies, imposts, charges, assessments, fees, deductions or withholdings, now or hereafter imposed, levied, collected, withheld or assessed by any Governmental Authority, and all interest, penalties or similar liabilities with respect thereto.

"<u>Termination Date</u>" means the date on which all Obligations (other than contingent indemnification obligations and expenses reimbursement obligations for which no claim has been made) have been paid in full in cash and the Commitment shall have terminated.

"Third Party" means any Person other than Holdings, the Borrower or any of its Subsidiaries.

"<u>Total Credit Exposure</u>" means, as to any Lender on any date, the aggregate outstanding principal amount of the Loans of such Lender after giving effect to any borrowings and prepayments or repayments of any Loans occurring on such date.

"<u>Trademark</u>" means any trademark, service mark, trade name, logo, symbol, trade dress, domain name, corporate name or other indicator of source or origin, and all applications and registrations therefor, together with all of the goodwill associated therewith.

"<u>Trademark Security Agreement</u>" means any Trademark Security Agreement executed and delivered to the Administrative Agent by Holdings, the Borrower or any of the Subsidiaries substantially in the form of Exhibit B to any Security Agreement, as amended, supplemented, amended and restated or otherwise modified from time to time.

"UCC" means the Uniform Commercial Code as in effect from time to time in the State of New York; <u>provided</u> that, if, with respect to any financing statement or by reason of any provisions of law, the perfection or the effect of perfection or non-perfection of the security interests granted to any Secured Party pursuant to the applicable Loan Document is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than New York, then "UCC" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of each Loan Document and any financing statement relating to such perfection or effect of perfection or non-perfection.

"United States" or "U.S." means the United States of America, its fifty states and the District of Columbia.

"Valor Investors" means (a) Valor IV Pharma Holdings, LLC or (b) any Controlled Investment Affiliate of any of the foregoing.

"Voting Agreement" means the Second Amended and Restated Voting Agreement, dated as of August 9, 2019, by and among the Company and certain of its stockholders, as amended,

supplemented, amended and restated or otherwise modified from time to time prior to the date hereof and as may be further amended, supplemented, amended and restated or otherwise modified from time to time after the date hereof in accordance with the terms thereof and hereof.

"<u>Voting Securities</u>" means, with respect to any Person, Capital Securities of any class or kind ordinarily having the power to vote for the election of directors, managers or other voting members of the governing body of such Person.

"<u>Wakix</u>" means the product known as of the date hereof as Wakix® that contains the active pharmaceutical ingredient pitolisant hydrochloride as its sole active ingredient.

"Wakix NCE" means the designation and approval by the FDA of Wakix as a new chemical entity in connection with the Wakix NDA.

"Wakix NDA" means New Drug Application Number N211150.

"Wakix Net Revenue" means, for any period, Net Revenue in respect of Wakix for such period.

"Wakix ODE" means the designation and approval by the FDA of Wakix as an orphan drug indicated for the treatment of excessive daytime sleepiness in adult patients with narcolepsy in connection with the Wakix NDA.

"wholly owned Subsidiary" means any direct or indirect Subsidiaries of Borrower, all of the outstanding Capital Securities of which (other than any director's qualifying shares or investments by foreign nationals mandated by applicable laws) is owned directly or indirectly by Borrower.

SECTION 1.2 <u>Use of Defined Terms</u>. Unless otherwise defined or the context otherwise requires, terms for which meanings are provided in this Agreement shall have such meanings when used in each other Loan Document and the schedules attached hereto.

SECTION 1.3 <u>Cross-References</u>. Unless otherwise specified, references in a Loan Document to any Article or Section are references to such Article or Section of such Loan Document, and references in any Article, Section or definition to any clause are references to such clause of such Article, Section or definition.

SECTION 1.4 Accounting and Financial Determinations. Unless otherwise specified, all accounting terms used in each Loan Document shall be interpreted, and all accounting determinations and computations thereunder (including under Section 8.4 and the definitions used in such calculations) shall be made, in accordance with GAAP, as in effect from time to time; provided that, if either the Borrower or the Required Lenders request an amendment to any provision hereof to eliminate the effect of any change occurring after the date hereof in GAAP or the application thereof on the operation of such provision, regardless of whether any such notice is given before or after such change in GAAP or the application thereof, then such provision shall be interpreted on the basis of GAAP in effect and applied immediately before

such change shall have become effective until such request shall have been withdrawn or such provision amended in accordance herewith (it being understood and agreed that the provisions of this proviso shall not apply to any requirement regarding the preparation or delivery of audited or unaudited financial statements under <u>Sections 7.1(b)</u> and <u>7.1(c)</u>). Unless otherwise expressly provided, all financial covenants and defined financial terms shall be computed on a consolidated basis for Holdings, the Borrower and the Subsidiaries, in each case without duplication.

ARTICLE II COMMITMENT AND BORROWING PROCEDURES

SECTION 2.1 <u>Commitment</u>. On the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the "<u>Loans</u>") on the Closing Date in an amount equal to (but not less than) such Lender's Commitment Amount. No amounts paid or prepaid with respect to the Loans may be reborrowed.

SECTION 2.2 <u>Borrowing Procedure</u>. The Borrower may irrevocably request that the Loans be made by delivering to the Administrative Agent a Loan Request on or before 10:00 a.m. on a Business Day at least three Business Days prior to the proposed Closing Date.

SECTION 2.3 <u>Funding</u>. After receipt of the Loan Request for the Loans, the Administrative Agent shall promptly notify each Lender of the amount of such Lender's portion of the Loans. Each Lender shall, on the Closing Date and subject to the terms and conditions hereof, make the requested proceeds of such Lender's portion of the Loans available to or as instructed by the Administrative Agent. Upon satisfaction of the applicable conditions set forth in <u>Article V</u>, the Administrative Agent shall make all funds so received available to the Borrower by wire transfer to the account the Borrower shall have specified in its Loan Request in an amount equal to (but not less than) the Lenders' Commitment Amount.

SECTION 2.4 <u>Reduction of the Commitment Amounts</u>. The Commitment Amount shall automatically and permanently be reduced to zero upon the Lenders funding of the Loans to Borrower on the Closing Date.

SECTION 2.5 <u>Incremental Commitments</u>. The Borrower, the Administrative Agent and the Lenders may agree, in their sole discretion, that one or more Lenders shall make, obtain or increase the amount of, its loans and commitments hereunder, in one or more series or tranches, on mutually agreed terms, pursuant to an amendment hereto agreed by the Borrower, the Administrative Agent and the Lenders.

ARTICLE III REPAYMENTS, PREPAYMENTS, INTEREST AND FEES

SECTION 3.1 <u>Repayments and Prepayments; Application</u>. The Borrower agrees that the Loans, and any fees or interest accrued or accruing thereon, shall be repaid and prepaid solely in U.S. dollars pursuant to the terms of this <u>Article III</u>.

SECTION 3.2 <u>Repayments and Prepayments</u>. The Borrower shall pay to the Administrative Agent for the benefit of the Lenders a portion of the then aggregate unpaid principal balance of the Loans as follows within 45 days of the end of each Fiscal Quarter; <u>provided</u> that, with respect to each repayment shown below, no such repayment shall be required to the extent one or both of the conditions (unless such condition is labelled as N/A) set forth in the corresponding columns are met as of such date:

Fiscal Quarter Ending	Amount of Loan Payment (as a percentage of the original principal amount thereof)	Wakix Net Revenue for such Fiscal Quarter as of the end of such Fiscal Quarter equals or exceeds		ene	Wakix Net Revenue for the twelve- month period ending as of the end of such Fiscal Quarter equals or exceeds	
March 31, 2020	15%	\$	1,380,257	\$	1,380,257	
June 30, 2020	15%	\$	4,701,758	\$	6,082,015	
September 30, 2020	15%	\$	9,528,646	\$	15,610,661	
December 31, 2020	15%	\$	15,195,337	\$	30,805,998	
March 31, 2021	15%	\$	20,433,421	\$	49,859,162	
June 30, 2021	15%	\$	30,748,185	\$	75,905,590	
September 30, 2021	15%	\$	40,216,550	\$	106,593,494	
December 31, 2021	15%	\$	50,871,677	\$	142,269,834	
For each Fiscal Quarter thereafter	15%	\$	50,871,677		N/A	

The Borrower shall also repay in full the unpaid principal amount of the Loans on the Maturity Date; <u>provided</u> that, at any time prior to the Maturity Date, payments and prepayments of the Loans shall or may (with respect to <u>clause (a)</u> below) also be made as set forth below:

- (a) The Borrower shall have the right, with at least three Business Days' notice to the Administrative Agent, at any time and from time to time to prepay any unpaid principal amount of the Loans, in whole or in part.
- (b) Within three Business Days of receipt by Holdings, the Borrower or any Subsidiary of any (i) Net Casualty Proceeds or (ii) Net Asset Sales Proceeds, the Borrower shall notify the Administrative Agent and the Lenders thereof. If requested by the Required Lenders, the Borrower shall within three Business Days of such request make a mandatory prepayment of the Loans, in an amount equal to 100% of such proceeds (or such lesser amount as the Required Lenders may specify on the date of such request).

(c) The Borrower shall repay the Loans in full immediately upon any acceleration of the Maturity Date thereof pursuant to Section 9.2 or Section 9.3, unless, pursuant to Section 9.3, only a portion of the Loans is so accelerated (in which case the portion so accelerated shall be so repaid).

SECTION 3.3 [Reserved].

SECTION 3.4 Interest Rate.

- (a) During any applicable Interest Period, Interest payable in cash by the Borrower shall accrue on the Loans during such Interest Period at a rate per annum equal to the LIBO Rate for such Interest Period, <u>plus</u> the Applicable Margin.
- (b) The interest rate shall be recalculated and, if necessary, adjusted for each Interest Period, in each case pursuant to the terms hereof.

SECTION 3.5 <u>Default Rate</u>. At all times commencing upon the date any Event of Default occurs, and continuing until such Event of Default is no longer continuing, the Applicable Margin shall be increased by 3.00% per annum.

SECTION 3.6 Payment Dates. Interest accrued on the Loans shall be payable in cash, without duplication:

- (a) on the Maturity Date therefor;
- (b) on the date of any payment or prepayment, in whole or in part, of principal outstanding on such Loan on the principal amount so paid or prepaid;
- (c) on the last day of each month; <u>provided</u> that if such day is not a Business Day, then such payment shall be made on the next succeeding Business Day; and
 - (d) on that portion of the Loans that is accelerated pursuant to Section 9.2 or Section 9.3, immediately upon such acceleration.

Interest accrued on the Loans or other monetary Obligations after the date such amount is due and payable (whether on the Maturity Date, upon acceleration or otherwise) shall be payable upon demand.

SECTION 3.7 <u>Repayment Premium</u>. Any repayment or prepayment of principal pursuant to this Article III (other than any repayments of principal made on the Maturity Date), shall be accompanied by the Repayment Premium.

SECTION 3.8 Exit Fee. Upon the prepayment or repayment of all or any portion of the principal of any Loans (or upon the date any such prepayment or repayment is required to be paid), whether on the Maturity Date, or pursuant to Section 3.2, Section 9.2, Section 9.3 or otherwise, the Borrower shall pay to the Administrative Agent for the ratable account of each Lender, in cash, on the date on

which such prepayment or repayment is paid or required to be paid, as the case may be, a fee (the "<u>Exit Fee</u>") in an amount equal to seven percent (7.00%) of the principal amount of the Loans prepaid, repaid, or required to be prepaid or repaid, as the case may be, on such date.

SECTION 3.9 [Reserved].

SECTION 3.10 [Reserved].

SECTION 3.11 <u>Administration Fee</u>. The Borrower will pay to the Administrative Agent, for the account of each Lender, a quarterly loan administration fee of \$10,000 (the "<u>Administration Fee</u>") payable in advance, with the first payment due and payable upon the Closing Date prorated with respect to the Fiscal Quarter in which the Closing Date occurs and successive payments payable on the last day of each Fiscal Quarter; <u>provided</u> that if such day is not a Business Day, then such payment shall be made on the next succeeding Business Day.

ARTICLE IV LIBO RATE AND OTHER PROVISIONS

SECTION 4.1 <u>Increased Costs, Etc.</u> The Borrower agrees to reimburse the Lenders for any increase in the cost to the Lenders of, or any reduction in the amount of any sum receivable by the Lenders in respect of, the Lenders' Commitments and the making, continuation or maintaining of the Loans hereunder that may arise in connection with any Change in Law, except for such changes with respect to increased capital costs and Taxes which are governed by <u>Section 4.2</u> and <u>Section 4.3</u>, respectively. The Administrative Agent shall notify the Borrower in writing of the occurrence of any such event, stating the reasons therefor and the additional amount required fully to compensate the Lenders for such increased cost or reduced amount. Such additional amounts shall be payable by the Borrower directly to the Administrative Agent for the accounts of the Lenders within thirty (30) days of its receipt of such notice, and such notice shall, in the absence of manifest error, be conclusive and binding on the Borrower; <u>provided</u> that the Borrower shall not be required to compensate any Lender pursuant to this <u>Section 4.1</u> for any such increased cost or reduced amount incurred by any Lender more than 180 days prior to the date the Borrower receives such notice from the Administrative Agent.

SECTION 4.2 <u>Increased Capital Costs</u>. If any Change in Law affects or would affect the amount of capital required or expected to be maintained by any Lender or any Person controlling such Lender, and such Lender determines (in good faith but in its sole and absolute discretion) that the rate of return on its or such controlling Person's capital as a consequence of the Commitments or the Loans made by it hereunder is reduced to a level below that which such Lender or such controlling Person could have achieved but for the occurrence of any such circumstance, then upon notice from time to time by such Lender to the Borrower, the Borrower shall within thirty (30) days following receipt of such notice pay directly to the Administrative Agent for the account of such Lender additional amounts sufficient to

compensate such Lender or any such controlling Person for such reduction in rate of return; <u>provided</u> that the Borrower shall not be required to compensate any Lender or such controlling Person pursuant to this <u>Section 4.2</u> for any such reduction in rate of return incurred by any Lender or any such controlling Person more than 180 days prior to the date the Borrower receives such notice from the Administrative Agent. A statement of such Lender as to any such additional amount or amounts shall, in the absence of manifest error, be conclusive and binding on the Borrower. In determining such amount, such Lender may use any method of averaging and attribution that it (in its reasonable discretion) shall deem applicable.

SECTION 4.3 <u>Taxes</u>. The Borrower covenants and agrees as follows with respect to Taxes.

- (a) Except as required by applicable Laws, any and all payments by the Borrower under each Loan Document shall be made without setoff, counterclaim or other defense, and free and clear of, and without deduction or withholding for or on account of, any Taxes. In the event that any Taxes are imposed and required to be deducted or withheld from any payment required to be made by Holdings, the Borrower or any of the Subsidiaries to or on behalf of the Lenders under any Loan Document, then:
 - (i) if such Taxes are Non-Excluded Taxes, the amount of such payment shall be increased as may be necessary so that such payment is made, after withholding or deduction for or on account of such Non-Excluded Taxes, in an amount that is not less than the amount provided for in such Loan Document; and
 - (ii) the Borrower or other applicable withholding agent shall withhold the full amount of such Taxes from such payment (as increased pursuant to $\underline{\text{clause }(\underline{a})(\underline{i})}$) and shall pay such amount to the Governmental Authority imposing such Taxes in accordance with applicable Laws.
- (b) In addition, the Borrower shall pay all Other Taxes imposed to the relevant Governmental Authority imposing such Other Taxes in accordance with applicable Laws.
- (c) As promptly as practicable after the payment of any Taxes or Other Taxes required to be paid by the Borrower under Section 4.3(a) or (b), and in any event within 45 days of any such payment being made, the Borrower shall furnish to the Administrative Agent a copy of an official receipt (or a certified copy thereof), a copy of the return reporting such payment, or other evidence of such payment reasonably satisfactory to the Administrative Agent evidencing the payment of such Taxes or Other Taxes.
- (d) Without duplication for amounts paid under <u>Section 4.3(a)</u>, the Borrower shall indemnify each Lender for any Non-Excluded Taxes and Other Taxes levied, imposed or assessed on (and whether or not paid directly by) such Lender

whether or not such Non-Excluded Taxes or Other Taxes are correctly or legally asserted by the relevant Governmental Authority. In addition, the Borrower shall indemnify each Lender for any incremental Taxes that may become payable by such Lender as a result of any failure of the Borrower to pay any Taxes required to be withheld or paid by the Borrower pursuant to <u>clauses (a) and (b)</u> when due to the appropriate Governmental Authority or to deliver to such Lender, pursuant to <u>clause (c)</u>, documentation evidencing the payment of Taxes or Other Taxes. With respect to indemnification for Non-Excluded Taxes and Other Taxes actually paid by each Lender or the indemnification provided under this <u>Section 4.3(d)</u>, such indemnification shall be made within 30 days after the date such Lender makes written demand therefor. The Borrower acknowledges that any payment made to any Lender or to any Governmental Authority in respect of the indemnification obligations of the Borrower provided in this <u>clause (d)</u> shall constitute a payment in respect of which the provisions of <u>clause (a)</u> and this <u>clause (d)</u> shall apply.

- (e) Each party's obligations under this <u>Section 4.3</u> shall survive the resignation or replacement of the Administrative Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all other Obligations.
- (f) The Lenders and the Borrower agree that the Loans are part of investment units issued within the meaning of Section 1273(c)(2) of the Code, which also includes the Lender Warrants. For all applicable income Tax purposes, the issue price of the investment units and the fair market value of the Lender Warrants in connection with the Loans of the Lenders shall be determined collectively by the Borrower and the Lenders, acting in good faith, at the time such Loans are issued to the Borrower. The "issue price" for the interest in the Loan of each Lender issued pursuant to this Agreement (and any Note issued in connection therewith) shall equal (i) the issue price of the investment units, minus (ii) the fair market value of the Lender Warrants issued in connection with such Lender's Loans. The Lenders and the Borrower agree that the allocation determined pursuant to this Section 4.3(f) will be used for purposes of Section 1273(c)(2) of the Code. The Borrower and the Lenders agree to make any determinations under Treasury Regulations §1.1273-2(h)(2) consistent with the foregoing and to file all required tax returns consistently with the foregoing, as applicable, except as otherwise required by applicable Laws.
- (g) <u>Original Issue Discount</u>. The Loans are deemed to be made with original issue discount for U.S. federal income tax purposes. Requests for information regarding the issue price, amount of original issue discount, issue date, and yield to maturity on the Loans shall be directed to the Borrower care of the Chief Financial Officer of the Borrower at 630 W Germantown Pike, Plymouth Meeting, PA 19462.
- (h) (i) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Administrative Agent, at the time or times reasonably requested by the Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Administrative

Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by the Borrower or the Administrative Agent, shall deliver such other documentation prescribed by applicable Laws or reasonably requested by the Borrower or the Administrative Agent as will enable the Borrower or the Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in paragraphs (h)(ii)(1), (ii) (2) and (ii)(4) of this Section) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

- (ii) Without limiting the generality of the foregoing,
 - (1) any Lender that is not a Foreign Lender shall deliver to the Borrower and the Administrative Agent on or about the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), executed copies of IRS Form W-9 certifying that such Lender is not subject to U.S. federal backup withholding tax;
 - (2) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Administrative Agent (in such number of copies as shall be requested by the recipient) on or about the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), whichever of the following is applicable:
 - (a) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;
 - (b) executed copies of IRS Form W-8ECI;

- (c) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c) (3)(A) of the Code, a "10 percent shareholder" of the Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to the Borrower as described in Section 881(c)(3)(C) of the Code (a "U.S. Tax Compliance Certificate") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or
- (d) to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; <u>provided</u> that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate on behalf of each such direct and indirect partner;
- (3) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Administrative Agent (in such number of copies as shall be requested by the recipient) on or about the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), executed copies of any other form prescribed by applicable Laws as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable Laws to permit the Borrower or the Administrative Agent to determine the withholding or deduction required to be made; and
- (4) if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to the Borrower and the Administrative Agent at the time or times prescribed by law and at such time or times reasonably requested by the Borrower or the Administrative Agent such documentation prescribed by applicable Law (including as prescribed by Section 1471(b) (3)(C)(i) of the Code) and such

additional documentation reasonably requested by the Borrower or the Administrative Agent as may be necessary for the Borrower and the Administrative Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (4), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Administrative Agent in writing of its legal inability to do so.

(i) If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section (including by the payment of additional amounts pursuant to this Section), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this Section with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this paragraph (i) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this paragraph (i), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this paragraph (i) the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This paragraph shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

SECTION 4.4 Payments, Computations; Proceeds of Collateral, Etc.

(a) Unless otherwise expressly provided in a Loan Document, all payments by the Borrower pursuant to each Loan Document shall be made without setoff, deduction or counterclaim not later than 2:00 p.m. on the date due in same day or immediately available funds, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Administrative Agent may from time to time direct in writing. Funds received after 2:00 p.m. on any day shall be deemed to have been received on the next succeeding Business Day and any applicable interest or fee shall continue to accrue. All interest and fees shall be

computed on the basis of the actual number of days occurring during the period for which such interest or fee is payable over a year comprised of 360 days. Payments due on other than a Business Day shall be made on the next succeeding Business Day and such extension of time shall be included in computing interest and fees in connection with that payment.

- (b) All amounts received as a result of the exercise of remedies under the Loan Documents (including from the proceeds of collateral securing the Obligations) or under applicable law shall be applied upon receipt to the Obligations in accordance with <u>Section 9.4</u>.
- (c) The obligations of the Lenders hereunder to make Loans and to make payments pursuant to $\frac{\text{Section } 10.4(c)}{\text{Section } 10.4(c)}$ are several and not joint. The failure of any Lender to make any Loan or to make any payment under $\frac{\text{Section } 10.4(c)}{\text{Section } 10.4(c)}$ on any date required hereunder shall not relieve any other Lender of its corresponding obligation to do so on such date, and no Lender shall be responsible for the failure of any other Lender to so make its Loan or to make its payment under $\frac{\text{Section } 10.4(c)}{\text{Section } 10.4(c)}$.
- (d) Nothing herein shall be deemed to obligate any Lender to obtain the funds for any Loan in any particular place or manner or to constitute a representation by any Lender that it has obtained or will obtain the funds for any Loan in any particular place or manner.
- (e) If any Lender shall, by exercising any right of setoff or otherwise, obtain payment in respect of any principal of or interest on its portion of any of the Loans or any Repayment Premium in connection therewith resulting in such Lender's receiving payment of a proportion of the aggregate amount of the Loans and accrued interest thereon and any Repayment Premium in connection therewith greater than its Applicable Percentage thereof as provided herein, then such Lender shall (x) notify the Administrative Agent of such fact and (y) purchase (for cash at face value) participations in the portions of the Loans of the other Lenders, or make such other adjustments as shall be equitable, so that the benefit of all such payments shall be shared by the Lenders ratably in accordance with the aggregate amount of principal of, accrued interest on and any Repayment Premium in connection with their respective portions of the Loans and other amounts owing them; provided that:
 - (i) if any such participations are purchased and all or any portion of the payment giving rise thereto is recovered, such participations shall be rescinded and the purchase price restored to the extent of such recovery, without interest; and
 - (ii) the provisions of this Section 4.4(e) shall not be construed to apply to (x) any payment made by or on behalf of the Borrower pursuant to and in accordance with the express terms of this Agreement or (y) any payment obtained by a Lender as consideration for the assignment of or sale of a participation in any of its portion of the Loans to any assignee or participant, other than an assignment to a Borrower or any Guarantor (as to which the provisions of this Section shall apply).

The Borrower, on behalf of itself and the Guarantors, hereby consents to the foregoing and agrees, to the extent it may effectively do so under applicable law, that any Lender acquiring a participation pursuant to the foregoing arrangements may exercise against the Borrower or such Guarantor rights of setoff and counterclaim with respect to such participation as fully as if such Lender were a direct creditor of the Borrower or such Guarantor in the amount of such participation. Each participant agrees to provide the documentation required by Section 4.3 to the Borrower and the Administrative Agent as though it were a Lender. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"). The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the Administrative Agent (in its capacity as Administrative Agent) shall have no responsibility for maintaining a Participant Register.

SECTION 4.5 <u>Setoff</u>. Each Lender shall, upon the occurrence and during the continuance of any Default described in <u>clauses</u> (<u>i)</u> through (<u>iv)</u> of <u>Section 9.1(h)</u> or, upon the occurrence and during the continuance of any other Event of Default, have the right to appropriate and apply to the payment of the Obligations owing to it (whether or not then due), and (as security for such Obligations) the Borrower hereby grants to each Lender a continuing security interest in, any and all balances, credits, deposits, accounts or moneys of the Borrower then or thereafter maintained with or on behalf of such Lender. Each Lender agrees promptly to notify the Borrower after any such appropriation and application made by such Lender; <u>provided</u> that, the failure to give such notice shall not affect the validity of such setoff and application. The rights of each Lender under this <u>Section 4.5</u> are in addition to other rights and remedies (including other rights of setoff under applicable law or otherwise) which such Lender may have.

SECTION 4.6 LIBO Rate Not Determinable.

(a) If prior to the commencement of any Interest Period for a Loan, the Administrative Agent reasonably determines (which determination shall be conclusive absent manifest error) that adequate and reasonable means do not exist for ascertaining the LIBO Rate for such Interest Period, then the Administrative Agent shall give notice thereof to the Borrower as promptly as practicable and, until the Administrative Agent notifies the Borrower that the circumstances giving rise to such notice no longer exist, (i) the Loans shall bear interest calculated pursuant to Section 3.4 but using the Prime Rate instead of the LIBO Rate and (ii) the continuation of any outstanding Loan or the extension of a new Loan hereunder shall be made with interest calculated pursuant to Section 3.4 but using the Prime Rate instead of the LIBO Rate.

(b) If at any time the Administrative Agent determines (which determination shall be conclusive absent manifest error) that (i) the circumstances set forth in Section 4.6(a) have arisen and such circumstances are unlikely to be temporary or (ii) the circumstances set forth in Section 4.6(a) have not arisen but the supervisor for the administrator of the LIBO Rate has made a public statement identifying a specific date after which the LIBO Rate shall no longer be used for determining interest rates for loans, then the Administrative Agent and the Borrower shall, acting in good faith, mutually establish an alternate rate of interest to that based on the LIBO Rate that gives due consideration to the then-prevailing market convention for determining a rate of interest for loans in the United States at such time, and the Administrative Agent and the Borrower shall enter into an amendment to this Agreement to reflect such alternate rate of interest and such other related changes as the Administrative Agent and the Borrower may reasonably determine to be appropriate. Until an alternate rate of interest shall be determined in accordance with this Section 4.6(b) (but, in the case of the circumstances described in clause (ii) of the first sentence of this Section 4.6(b), only to the extent the LIBO Rate for such Interest Period is not available or published at such time on a current basis), Section 4.6(a) shall be applicable.

ARTICLE V CONDITIONS TO MAKING THE LOANS

SECTION 5.1 <u>Credit Extensions</u>. The obligation of each Lender to make its portion of the Loans shall be subject to the execution and delivery of this Agreement by the parties hereto, the delivery of a Loan Request as requested pursuant to <u>Section 2.3</u>, and the satisfaction of each of the conditions precedent set forth below in this Article.

SECTION 5.2 Secretary's Certificate, Etc. The Administrative Agent and each Lender shall have received from Holdings, the Borrower and each Subsidiary party to an Investment Document, (i) a copy of a good standing certificate, dated a date reasonably close to the Closing Date, for each such Person and (ii) a certificate, dated as of the Closing Date, duly executed and delivered by such Person's Secretary or Assistant Secretary, managing member or general partner, as applicable, certifying as to

(a) resolutions of each such Person's board of directors (or other managing body, in the case of a Person other than a corporation) and any other corporate resolutions required by applicable Law or pursuant to such Person's Organic Documents, each of which shall be then in full force and effect, authorizing the execution, delivery and performance of each Investment Document to be executed by such Person and the transactions contemplated hereby and thereby;

- (b) the incumbency and signatures of those of its officers, managers, managing member or general partner, as applicable, authorized to act with respect to each Investment Document to be executed by such Person; and
 - (c) the full force and validity of each Organic Document of such Person and copies thereof;

upon which certificates the Administrative Agent and each Lender may conclusively rely until it shall have received a further certificate of the Secretary, Assistant Secretary, managing member or general partner, as applicable, of any such Person canceling or amending the prior certificate of such Person.

SECTION 5.3 <u>Closing Date Certificate</u>. The Administrative Agent and each Lender shall have received a Closing Date Certificate, dated as of the Closing Date and duly executed and delivered by an Authorized Officer of the Borrower, in which certificate the Borrower shall agree and acknowledge that the statements made therein shall be deemed to be true and correct representations and warranties of the Borrower as of such date, and, at the time such certificate is delivered, such statements shall in fact be true and correct, and such statements shall include that (a) the representations and warranties set forth in each Investment Document shall, in each case, be true and correct, (b) no Default shall have then occurred and be continuing, or would result from the Loans to be advanced on the Closing Date and (c) all of the conditions set forth in this Article V have been satisfied.

SECTION 5.4 <u>Payment of Outstanding Indebtedness</u>, <u>Etc</u>. All Indebtedness identified in <u>Schedule 8.2(b)</u>, together with all interest, all prepayment premiums and all other amounts due and payable with respect thereto (collectively, shall have been paid in full from the proceeds of the Loans and the commitments in respect of such Indebtedness shall have been terminated, and all Liens securing payment of any such Indebtedness shall have been released and the Administrative Agent and each Lender shall have received all UCC Form UCC-3 termination statements or other instruments (including customary payoff letters) as may be suitable or appropriate in connection therewith (the "<u>Existing Debt Refinancing</u>").

SECTION 5.5 <u>Delivery of Note</u>. Each Lender shall have received a Note duly executed and delivered by an Authorized Officer of the Borrower.

SECTION 5.6 Financial Information, Etc. The Administrative Agent and each Lender shall have received

- (a) audited consolidated financial statements of Holdings, the Borrower and the Subsidiaries for each of the fiscal years ended December 31, 2017, and December 31, 2018; and
- (b) unaudited consolidated balance sheets of Holdings, the Borrower and the Subsidiaries for each fiscal quarter ended after December 31, 2018, together with the related consolidated statement of operations, shareholder's equity and cash flows for the twelve months then ended.

SECTION 5.7 <u>Compliance Certificate</u>. The Lenders and the Administrative Agent shall have received an initial Compliance Certificate as of the Closing Date and as to such items therein as any Lender reasonably requests, dated the Closing Date, duly executed (and with all schedules thereto duly completed) and delivered by the chief financial or accounting Authorized Officer of the Borrower.

SECTION 5.8 <u>Solvency, Etc.</u> The Lenders and the Administrative Agent shall have received a solvency certificate duly executed and delivered by the chief financial or accounting Authorized Officer of Holdings and the Borrower, dated as of the Closing Date, in form and substance reasonably satisfactory to the Lenders and the Administrative Agent.

SECTION 5.9 <u>Guarantee</u>. The Lenders and the Administrative Agent shall have received executed counterparts of the Guarantee, dated as of the date hereof, duly executed and delivered by Holdings and each Subsidiary.

SECTION 5.10 <u>Security Agreements</u>. The Lenders and the Administrative Agent shall have received executed counterparts of the Security Agreement, dated as of the date hereof, duly executed and delivered by Holdings, the Borrower and each Subsidiary, together with

- (a) certificates (in the case of Capital Securities that are securities (as defined in the UCC)) evidencing all of the issued and outstanding Capital Securities owned by Holdings, the Borrower or any Subsidiary in the Subsidiaries, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank, or, in the case of Capital Securities that are uncertificated securities (as defined in the UCC), confirmation and evidence reasonably satisfactory to the Administrative Agent and the Lenders that the security interest therein has been (or will be) perfected by the Administrative Agent for the benefit of the Secured Parties in accordance with Articles 8 and 9 of the UCC;
- (b) financing statements suitable in form for naming Holdings, the Borrower and each Subsidiary as a debtor and the Administrative Agent as the secured party, or other similar instruments or documents to be filed under the UCC of all jurisdictions as may be necessary or, in the opinion of the Administrative Agent or any Lender, desirable to perfect the security interests of the Administrative Agent and the other Secured Parties pursuant to the Security Agreement;
- (c) UCC Form UCC-3 termination statements, if any, necessary to release all Liens and other rights of any Person (i) in any assets of Holdings, the Borrower or any Subsidiary, or (ii) securing any of the Indebtedness identified in Schedule 8.2(b), together with such other UCC Form UCC-3 termination statements as the Administrative Agent or any Lenders may reasonably request from Holdings, the Borrower or any Subsidiary; and

(d) evidence that all deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts of Holdings, the Borrower and each Subsidiary are Controlled Accounts (other than Excluded Accounts).

SECTION 5.11 Intellectual Property Security Agreements. The Administrative Agent and the Lenders shall have received a Patent Security Agreement, a Copyright Security Agreement and a Trademark Security Agreement, as applicable, each dated as of the Closing Date, duly executed and delivered by Holdings, the Borrower or any Subsidiary that, pursuant to the Security Agreement, is required to provide such intellectual property security agreements to the Administrative Agent for the benefit of the Secured Parties.

SECTION 5.12 <u>Opinions of Counsel</u>. The Administrative Agent and the Lenders shall have received an opinion, dated the Closing Date and addressed to the Secured Parties, from Katten Muchin Rosenman LLP, counsel to Holdings, the Borrower and the Subsidiaries, in form and substance satisfactory to the Administrative Agent and the Lenders.

SECTION 5.13 <u>Insurance</u>. The Administrative Agent and the Lenders shall have received certified copies of the insurance policies (or binders in respect thereof), from one or more insurance companies reasonably satisfactory to the Administrative Agent and the Lenders, evidencing coverage required to be maintained pursuant to <u>Section 7.4</u>, with the Administrative Agent named as loss payee or additional insured, as applicable.

SECTION 5.14 <u>Closing Fees, Expenses, Etc</u>. Each Lender and the Administrative Agent shall have received for its own account all fees, costs and expenses due and payable pursuant to <u>Section 10.4</u>.

SECTION 5.15 <u>Anti-Terrorism Laws</u>. Each Lender and the Administrative Agent shall have received, as applicable, all documentation and other information required by bank regulatory authorities under applicable "know your customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act.

SECTION 5.16 <u>Investment Documents</u>. The Administrative Agent shall have received executed counterparts of this Agreement, the Lender Warrants and the other Investment Documents, each properly executed by Holdings or the Borrower, as applicable, and each other party to such Investment Documents.

ARTICLE VI REPRESENTATIONS AND WARRANTIES

In order to induce the Lenders and the Administrative Agent to enter into this Agreement and to make the Loans hereunder, the Borrower represents and warrants to the Lenders and the Administrative Agent that:

SECTION 6.1 <u>Organization</u>, <u>Etc</u>. Holdings, the Borrower and each Subsidiary (a) is validly organized and existing and in good standing under the laws of the jurisdiction of its incorporation or organization, is duly qualified to do business and is in good standing as a foreign entity in each jurisdiction where the nature of its business requires such qualification (unless the failure to so qualify as a foreign entity would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect), and (b) has full power and authority and holds all requisite governmental licenses, permits and other material approvals required (i) to enter into and perform its Obligations under each Investment Document to which it is a party, and (ii) to own and hold under lease its material property and to conduct its business substantially as currently conducted by it.

SECTION 6.2 <u>Due Authorization, Non-Contravention, Etc</u>. The execution, delivery and performance by Holdings, the Borrower and each Subsidiary of each Investment Document executed or to be executed by it are in each case within such Person's corporate or organizational powers, have been duly authorized by all necessary corporate or organizational action, and do not

- (a) contravene (i) Holdings', the Borrower's or any Subsidiary's Organic Documents, (ii) in any material respect, any court decree or order binding on or affecting Holdings, the Borrower or any Subsidiary or (iii) in any material respect, any law or governmental regulation binding on or affecting Holdings, the Borrower or any Subsidiary; or
- (b) result in (i) or require the creation or imposition of any Lien on Holdings', the Borrower's or any Subsidiary's properties (except as permitted by this Agreement) or (ii) a material default under any material contract, agreement, or instrument binding on or affecting Holdings, the Borrower or any Subsidiary.

SECTION 6.3 <u>Government Approval, Regulation, Etc.</u> No authorization, approval, clearance or other action by, and no notice to or filing with, any Governmental Authority or other Person (other than those that have been, or on the Closing Date will be, duly obtained or made and which are, or on the Closing Date will be, in full force and effect) is required for the due execution, delivery or performance by Holdings, the Borrower or any Subsidiary of any Investment Document to which it is a party.

SECTION 6.4 <u>Validity, Etc</u>. Each Investment Document to which Holdings, the Borrower or any Subsidiary is a party constitutes the legal, valid and binding obligations of such Person enforceable against such Person in accordance with its respective terms (except, in any case, as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally and by principles of equity).

SECTION 6.5 <u>Financial Information</u>. The financial statements of Holdings, the Borrower and the Subsidiaries furnished to the Administrative Agent and the Lenders pursuant to <u>Sections 5.6</u> and <u>7.1</u> have been prepared in accordance with

GAAP, consistently applied, and present fairly the consolidated financial condition of the Persons covered thereby as at the dates thereof and the results of their operations for the periods then ended, subject to customary year-end adjustments and the absence of footnotes in the case of the previously-delivered statements of the type described in <u>Section 5.6(b)</u>.

SECTION 6.6 No Material Adverse Change. There has been no material adverse change in the business, financial condition, operations (including the results thereof), performance or properties of Holdings, the Borrower or any Subsidiary since December 31, 2018.

SECTION 6.7 Litigation, Labor Matters and Environmental Matters.

- (a) Except as described on Schedule 6.7(a), there are no actions, suits or proceedings by or before any arbitrator or Governmental Authority pending against or, to the knowledge of the Borrower, threatened, against or affecting Holdings, the Borrower or any Subsidiary (i) as to which there is a reasonable likelihood of an adverse determination and that, if adversely determined, would reasonably be expected, individually or in the aggregate, to result in liabilities in excess of \$1,000,000 or (ii) that would reasonably be likely to materially and adversely affect this Agreement or the transactions contemplated hereby.
- (b) There are no labor controversies pending against or, to the knowledge of the Borrower, threatened against or affecting Holdings, the Borrower or any Subsidiary (i) that would reasonably be expected, individually or in the aggregate, to result in liabilities in excess of \$1,000,000 or (ii) that would reasonably be likely to adversely affect this Agreement or the transactions contemplated hereby.
- (c) None of Holdings, the Borrower or any Subsidiary (i) has failed to comply with any Environmental Law or to obtain, maintain or comply with any Permit under or in connection with any Environmental Law ("Environmental Permit"), (ii) is or has been subject to any Environmental Liability, (iii) has received notice of any Environmental Liability, or (iv) knows of any basis for any Environmental Liability, in each case of clauses (i) through (iv) above, which would reasonably be expected to have a Material Adverse Effect.

SECTION 6.8 <u>Subsidiaries</u>. As of the Closing Date, the Borrower has no Subsidiaries except those Subsidiaries that are identified in <u>Schedule 6.8</u> (which Schedule also identifies the direct and indirect owners of the Capital Securities of such Subsidiaries).

SECTION 6.9 Ownership of Properties. Holdings, the Borrower and each Subsidiary owns (i) in the case of owned real property, good and marketable fee title to, and (ii) in the case of owned personal property, good and valid title to, or, in the case of leased real or personal property, valid and enforceable leasehold interests (as the case may be) in, all of its material properties and assets, tangible and intangible, of any nature whatsoever, free and clear in each case of all Liens or claims, except for Liens permitted pursuant to Section 8.3.

SECTION 6.10 <u>Taxes</u>. Holdings, the Borrower and each Subsidiary has filed all U.S. federal income and all other material tax returns and reports required by applicable Laws to have been filed by it and has paid all Taxes reported thereon as due and payable and all other material Taxes due and owing by it, except any such Taxes which are being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP shall have been set aside on its books.

SECTION 6.11 Benefit Plans, Etc. Except as would not reasonably be expected to result in a Material Adverse Effect: (a) none of Holdings, the Borrower or any of the Subsidiaries or any of their respective ERISA Affiliates sponsors, maintains, contributes to, is required to contribute to, or has any actual or potential liability with respect to, any Benefit Plan, (b) none of Holdings, the Borrower or any of the Subsidiaries is a party to any collective bargaining agreement, and none of the employees of Holdings, the Borrower or any of the Subsidiaries are subject to any collective bargaining agreement, (c) each "employee benefit plan" as defined in section 3(3) of ERISA that provides retirement benefits, is sponsored by Holdings, the Borrower or any of their ERISA Affiliates, and is intended to be tax qualified under section 401 of the Code has a determination letter or opinion letter from the Internal Revenue Service on which it is entitled to rely, and no assets of any such plan are invested in Capital Securities of Holdings or the Borrower and (d) each employee benefit plan, program or arrangement sponsored, maintained, contributed to or required to be contributed to by Holdings, the Borrower or any Subsidiary has complied, both in form and in operation, with its terms and applicable Law.

SECTION 6.12 Accuracy of Information. None of the information heretofore or contemporaneously furnished in writing to the Administrative Agent or any Lender by or on behalf of Holdings, the Borrower or any Subsidiary in connection with any Investment Document or any transaction contemplated hereby contains any material misstatement of a material fact, or omits to state any material fact necessary to make any information, in light of the circumstances under which they were made, not misleading; provided that, with respect to projected financial information and other forward-looking information, (i) Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time, (ii) such information is not to be viewed as facts, is not a guarantee of financial performance, and is subject to significant uncertainties and contingencies, many of which are beyond the control of Holdings, the Borrower and the Subsidiaries; (iii) no assurance can be given that any particular projections will be realized; and (iv) actual results during the periods covered thereby may differ from the results set forth in such information and such differences may be material.

SECTION 6.13 <u>Regulations U and X</u>. None of Holdings, the Borrower or any Subsidiary is engaged in the business of extending credit for the purpose of buying or carrying margin stock, and no proceeds of the Loans will be used to purchase or carry

margin stock or otherwise for a purpose which violates, or would be inconsistent with, F.R.S. Board Regulation U or Regulation X. Terms for which meanings are provided in F.R.S. Board Regulation U or Regulation X or any regulations substituted therefor, as from time to time in effect, are used in this Section with such meanings.

SECTION 6.14 <u>Solvency</u>. The Borrower, individually, and Holdings, the Borrower and its Subsidiaries taken as a whole, on a consolidated basis, both before and after giving effect to the Loans, are Solvent.

SECTION 6.15 Intellectual Property.

- (a) <u>Schedule 6.15(a)(1)</u> sets forth a complete and accurate list as of the Closing Date of all (i) issued Patents and any Patent applications,(ii) registered and material unregistered Trademarks (including domain names) and any pending registrations for Trademarks, and (iii) any other registered Intellectual Property, in each case owned by Holdings, the Borrower or any of the Subsidiaries. For each item of Intellectual Property listed on <u>Schedule 6.15(a)(1)</u>, the Borrower has, where relevant, indicated (A) the countries in each case in which such item is registered, (B) the application numbers, (C) the registration or patent numbers, (D) with respect to the Patents, the expected expiration date of the issued Patents and (E) the owner of such item of Intellectual Property. <u>Schedule 6.15(a)(2)</u> sets forth a list as of the Closing Date of all material license agreements pursuant to which Holdings, the Borrower or any Subsidiary licenses any Intellectual Property from any Third Party.
- (b) The Owned Intellectual Property and Licensed Intellectual Property together constitute all Intellectual Property necessary for the operation of the business of Holdings, the Borrower and the Subsidiaries as currently conducted in all material respects.
- (c) Holdings, the Borrower or a Subsidiary owns, has a valid license or rights in any other form to all rights associated with the Owned Intellectual Property and Licensed Intellectual Property (as applicable), and Holdings, the Borrower or a Subsidiary owns the Owned Intellectual Property and holds, to the knowledge of the Borrower, its rights under the Licensed Intellectual Property free and clear of any and all Liens other than Liens permitted pursuant to <u>Section 8.3</u> and all Owned Intellectual Property and, to the knowledge of the Borrower, Licensed Intellectual Property, is in full force and effect, and has not expired, lapsed or been forfeited, cancelled or abandoned.
- (d) Each of Holdings, the Borrower and the Subsidiaries, as applicable, has taken commercially reasonable actions to maintain and protect the Owned Intellectual Property and the Licensed Intellectual Property and there are no unpaid maintenance or renewal fees payable by Holdings, the Borrower or any of the Subsidiaries that are currently overdue for any of such registered Intellectual Property.

- (e) There is no actual or threatened (in writing or, to the knowledge of Borrower, orally) proceeding in any court, patent office, Governmental Authority, arbitral body or elsewhere challenging the validity or enforceability of any Owned Intellectual Property or, to the knowledge of the Borrower, any Licensed Intellectual Property, none of Holdings, the Borrower or any of the Subsidiaries is involved in any such proceeding with any Person and none of the Owned Intellectual Property or, to the knowledge of the Borrower, the Licensed Intellectual Property is the subject of any material Other Administrative Proceeding.
- (f) To the knowledge of the Borrower, (A) the Owned Intellectual Property and the Licensed Intellectual Property is valid, enforceable and subsisting and (B) no event has occurred, and nothing has been done or omitted to have been done, that would affect the validity or enforceability of such Intellectual Property.
- (g) Each of Holdings, the Borrower and each Subsidiary, as applicable, is the sole and exclusive owner of all right, title and interest in and to all Owned Intellectual Property that is owned by it.
- (h) To the knowledge of the Borrower, no Third Party is committing any act of Infringement of any Intellectual Property listed, or required to be listed, on Schedule 6.15(a)(1) or Schedule 6.15(a)(2).
- (i) With respect to each license agreement listed on <u>Schedule 6.15(a)(2)</u>, such license agreement (i) is in full force and effect and is binding upon and enforceable against Holdings, the Borrower and the Subsidiaries party thereto and, to the knowledge of the Borrower, all other parties thereto in accordance with its terms, (ii) has not been amended or otherwise modified, except as set forth on <u>Schedule 6.15(a)(2)</u>, and (iii) has not, to the knowledge of the Borrower, suffered a default or breach thereunder. To the knowledge of the Borrower, none of Holdings, the Borrower or any of the Subsidiaries has taken or omitted to take any action that would permit any other Person party to any such license agreement to have, and no such Person otherwise has, any defenses, counterclaims, termination rights or rights of setoff thereunder.
- (j) Except as set forth on Schedule 6.15(j), none of Holdings, the Borrower or any of the Subsidiaries has received written notice from any Third Party alleging that the conduct of its business (including the development, manufacture, use, sale or other commercialization of any Product) Infringes any Intellectual Property of that Third Party and, to the knowledge of the Borrower, the conduct of its business and the business of the Subsidiaries (including the development, manufacture, use, sale or other commercialization of any Product) does not Infringe any Intellectual Property of any Third Party.
- (k) Holdings, the Borrower and the Subsidiaries have used commercially reasonable efforts and precautions to protect their respective commercially significant unregistered Intellectual Property.

SECTION 6.16 Material Agreements and Key Contracts.

- (a) Set forth on Schedule 6.16 is a complete and accurate list as of the Closing Date of all Material Agreements and Key Contracts (other than Designated Key Contracts), in each case of Holdings, the Borrower or any of the Subsidiaries, with an adequate description of the parties thereto and amendments and modifications thereto. Each such Material Agreement and each Key Contract (i) is in full force and effect and the legal, valid and binding obligation of the parties thereto, enforceable against Holdings, the Borrower and the Subsidiaries party thereto and, in the case of any Material Agreement or Key Contract, to the knowledge of Borrower (other than in respect of the License Agreement), all other parties thereto in accordance with its terms and (ii) has not been amended or otherwise modified. (A) None of Holdings, the Borrower or any of the Subsidiaries is, in any material respect, in breach or in default (after giving effect to any grace or cure periods) under any Material Agreement or Key Contract, nor has any of Holdings, the Borrower or any of the Subsidiaries taken any action that would permit any other Person party to any Material Agreement or Key Contract to have, and no such Person otherwise has, any defenses, counterclaims, termination rights or rights of setoff thereunder and (B) to the knowledge of the Borrower, no such other Person party to such Material Agreement or Key Contract is, in any material respect, in breach or in default (after giving effect to any grace or cure periods) thereunder.
- (b) The Borrower has provided to the Administrative Agent and the Lenders full, complete and correct copies of the Key Contracts (including all exhibits and schedules thereto).

SECTION 6.17 <u>Permits</u>. Except as would not reasonably be expected to result in a Material Adverse Effect, (i) Holdings, the Borrower and the Subsidiaries have all Permits, including Key Permits and Environmental Permits, necessary or required for the ownership, operation and conduct of their business and the distribution of the Product and (ii) all such Permits are validly held and there are no defaults thereunder.

SECTION 6.18 Regulatory Matters.

(a) All Key Permits held by Holdings, the Borrower and the Subsidiaries are (i) legally and beneficially owned exclusively by Holdings, the Borrower or such Subsidiary, free and clear of all Liens other than Liens permitted pursuant to Section 8.3, and (ii) validly registered and on file with the applicable Governmental Authority, in compliance with all filing and maintenance requirements (including any fee requirements) thereof, and are in good standing, valid and enforceable with the applicable Governmental Authority. All notices, registrations and listings, supplemental applications or notifications, reports (including reports of adverse experiences) and other filings required to be filed by Holdings, the Borrower, the Subsidiaries or, to the knowledge of the Borrower, received from any of their respective suppliers with respect to any Product have been filed with the FDA and all other applicable Governmental Authorities. To the knowledge of the Borrower, the factual basis for the application to the FDA in respect of, and leading to, the Wakix

ODE was true, correct and complete in all material respects as of the date such factual basis was represented to the FDA and as of the date such factual basis was required to be represented to the FDA, and no misstatements or omissions in such factual basis have arisen between such dates and the date hereof. None of Holdings, the Borrower or any of the Subsidiaries has received any written notice that any Key Permits have been or are being revoked, withdrawn, suspended, limited or challenged.

- (b) (i) Except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect, the Products, as well as the business of Holdings, the Borrower and the Subsidiaries, comply with (A) all applicable Laws, including, without limitation, all applicable requirements of the FD&C Act, the PHSA and similar state Laws and (B) all Product Authorizations and other Key Permits; (ii) none of Holdings, the Borrower and the Subsidiaries, nor, to the knowledge of the Borrower, their respective suppliers, have received any inspection reports, warning letters or untitled letters with respect to any Product of Holdings, the Borrower and the Subsidiaries, from any Governmental Authority that assert a lack of compliance with the FD&C Act, the PHSA and similar state Laws; (iii) none of Holdings, the Borrower or any of the Subsidiaries has received any written notice of, or otherwise have knowledge of, any pending regulatory enforcement action, investigation or inquiry against Holdings, the Borrower or any of the Subsidiaries, or any of their respective suppliers with respect to the Products, and, to the knowledge of the Borrower, there is no basis for any adverse regulatory action against Holdings, the Borrower or any of the Subsidiaries or their respective suppliers, with respect to the Products; and (iv) without limiting the foregoing, (A) to the knowledge of the Borrower (1) there have been no Product recalls, safety alerts, withdrawals, clinical holds, marketing suspensions or removals, undertaken or issued by any Person, whether or not at the request, demand or order of any Governmental Authority or otherwise, with respect to any Product, (2) no such Product recalls, safety alerts, corrections, withdrawals, marketing suspensions or removals have been requested, demanded or ordered by any Governmental Authority, and, to the knowledge of the Borrower, there is no basis for the issuance of any such product recalls, safety alerts, corrections, withdrawals, marketing suspensions or removals by any Person with respect to any Products, and (B) none of Holdings, the Borrower or any of the Subsidiaries has received any written notice of, and does not otherwise have knowledge of, any criminal, injunctive, seizure, detention or civil penalty actions that have at any time been commenced or threatened in writing by any Governmental Authority with respect to or in connection with any Products, or any consent decrees (including plea agreements) which relate to any Products, and, to the knowledge of the Borrower, there is no basis for the commencement for any criminal injunctive, seizure, detention or civil penalty actions by any Governmental Authority relating to the Products or for the issuance of any consent decrees. None of Holdings, the Borrower and the Subsidiaries nor, to the knowledge of the Borrower, any of their respective suppliers is employing or utilizing the services of any individual who has been debarred under any FDA regulations.
- (c) All clinical trials conducted by or, to the knowledge of Borrower, on behalf of Holdings, the Borrower and the Subsidiaries with respect to any Product

have been conducted in compliance with cGCPs. None of Holdings, the Borrower and the Subsidiaries has received any written notice from FDA or any other Governmental Authority alleging any non-compliance with cGCPs or otherwise terminating or suspending any clinical trial (in-whole or in-part) conducted by or on behalf of Holdings, the Borrower and the Subsidiaries with respect to any Product. No clinical trial conducted by or, to the knowledge of the Borrower, on behalf of Holdings, the Borrower and the Subsidiaries with respect to any Product has used any clinical investigator who has been disqualified under FDA regulations.

- (d) With respect to Products, (i) all design, manufacturing, storage, distribution, packaging, labeling, sale, recordkeeping and other activities by Holdings, the Borrower or any of its Subsidiaries and, to the knowledge of the Borrower, their respective suppliers relating to the Products have been conducted, and are currently being conducted, in compliance with the applicable requirements of the FD&C Act, the PHSA and other requirements of the FDA and all other applicable Governmental Authorities, including, without limitation, cGMPs and adverse event reporting requirements, and (ii) none of Holdings, the Borrower or any of its Subsidiaries, or, to the knowledge of the Borrower, any of their respective suppliers, has received written notice or threat of commencement of action by any Governmental Authority to withdraw its approval of to enjoin production of the Products at any facility, or otherwise to seize any Product. To the knowledge of Borrower, no Product in the inventory of Holdings, the Borrower or any of its Subsidiaries, or otherwise currently in commercial distribution is adulterated or misbranded. All advertising or other promotion of all Products by Holdings, the Borrower or any of its Subsidiaries has been conducted in compliance with applicable FDA requirements for advertising and promotion of pharmaceuticals.
- (e) All manufacturing facilities owned or operated by Holdings, the Borrower or any of the Subsidiaries, or, to the knowledge of the Borrower, used in the production of any Product, are and have been operated in compliance with cGMPs and all other applicable Laws. To the knowledge of the Borrower, the FDA has not issued any written Form 483, Warning Letter, or untitled letter with respect to any such facility, or otherwise alleged any non-compliance with cGMPs.
- (f) The Borrower has made available to the Lenders all written material adverse event reports and communications to or from FDA (if any) and other relevant Governmental Authorities of which it has or had a copy, including written inspection reports, warning letters, untitled letters, and material reports and studies, other than opinions of counsel that are attorney-client privileged, with respect to regulatory matters relating to Holdings, the Borrower and the Subsidiaries, the conduct of their business, the operation of any manufacturing facilities owned or operated by Holdings, the Borrower or any of the Subsidiaries, and the Products. The Borrower has made available to the Lenders all Key Permits and material written correspondence submitted to or received from FDA, CMS or other Governmental Authority (including minutes and official contact reports relating to any material communications with any Governmental Authority) of which it has or had a copy.

- (g) All studies, tests and preclinical and clinical trials conducted relating to the Products by or, to the knowledge of Borrower, on behalf of Holdings, the Borrower or any of and the Subsidiaries and, to the knowledge of the Borrower, their respective licensees, licensors and third party services providers and consultants, have been conducted, and are currently being conducted, in full compliance with all applicable Laws, including, but not limited to, the FD&C Act, the PHSA, current good clinical practices and, to the extent required by FDA guidances and regulations, current good laboratory practices, except to the extent that the failure to do so would not reasonably be expected to result in a Material Adverse Effect. Material written summaries related to such studies, tests and trials have been made available to the Lenders. To the knowledge of the Borrower, the summaries and descriptions of any of the foregoing provided to the Lenders are accurate in all material respects and contain no material omissions. None of Holdings, the Borrower and the Subsidiaries, or, to the knowledge of the Borrower, any of their respective licensees, licensors or third party services providers or consultants, has received from the FDA or other applicable Governmental Authority any written notices or correspondence requiring the termination, suspension, material modification or clinical hold of any studies, tests or clinical trials with respect to or in connection with the Products.
- (h) There has been no material untrue statement of fact and no fraudulent statement made by Holdings, the Borrower or any of the Subsidiaries, or, to the Borrower's knowledge, any of their respective agents or representatives to the FDA or any other Governmental Authority, and there has been no failure to disclose any material fact required to be disclosed to the FDA or any other Regulatory Agency.
- (i) There is no arrangement relating to Holdings, the Borrower or the Subsidiaries providing for any rebates, kickbacks or other forms of compensation that are unlawful to be paid to any Person in return for the referral of business or for the arrangement for recommendation of such referrals. All billings by Holdings, the Borrower and the Subsidiaries for their services have been true and correct in all material respects and are in compliance in all material respects with all applicable Laws, including the Federal False Claims Act or any applicable state false claim or fraud law. None of Holdings, the Borrower and the Subsidiaries has received any written notice from the United States Department of Justice, any U.S. Attorney, any State Attorney General, or other similar Governmental Authority alleging any violation of the Federal Anti-kickback Statute, the Federal False Claims Act, the Foreign Corrupt Practices Act, any applicable federal Laws, or similar state or foreign Laws.
- (j) The transactions contemplated by the Investment Documents (or contemplated by the conditions to effectiveness of any Investment Document) will not impair Holdings', the Borrower's or any of the Subsidiaries' ownership of or rights under (or the license or other right to use, as the case may be) any Key Permits relating to the Products.
- (k) No right of Holdings, the Borrower or any of the Subsidiaries to receive reimbursements pursuant to any government program or private program has ever

been terminated or otherwise adversely affected as a result of any investigation or enforcement action, whether by any Governmental Authority or other Third Party, and none of Holdings, the Borrower or any Subsidiary has been the subject of any inspection, investigation, or audit, by any Governmental Authority for the purpose of any alleged improper activity.

(l) None of Holdings, the Borrower or any of the Subsidiaries, nor, to the Borrower's knowledge, any individual who is an officer, director, manager, employee, agent or managing agent of Holdings, the Borrower or any of the Subsidiaries has been convicted of, or, to the Borrower's knowledge, charged with or investigated for any federal or state health program-related offense or any other offense related to healthcare or been excluded or suspended from participation in any such program; or, to the Borrower's knowledge, within the past five (5) years, has been convicted of, or, to the Borrower's knowledge, charged with or investigated for a violation of Laws related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, obstruction of an investigation or controlled substances, or has been subject to any judgment, stipulation, order or decree of, or criminal or civil fine or penalty imposed by, any Governmental Authority related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, obstruction of an investigation or controlled substances. None of Holdings, the Borrower or any of the Subsidiaries, nor, to the Borrower's knowledge, any individual who is an officer, director, employee, agent or managing agent of Holdings, the Borrower or any of the Subsidiaries has been convicted of any crime that has resulted or would reasonably be expected to result in a debarment under 21 U.S.C. Section 335a. No debarment proceedings under any FDA regulation in respect of the business of Holdings, the Borrower or any of the Subsidiaries are pending or, to the Borrower's knowledge, threatened against Holdings, the Borrower, any of the Subsidiaries or, to the knowledge of the Borrower, any individual who is an officer, director, manager, employee, agent or managing agent of Holdings, the Borrower or any of the Subsidiaries.

SECTION 6.19 <u>Transactions with Affiliates</u>. As of the Closing Date, none of Holdings, the Borrower or any Subsidiary is a party to any contract or agreement (including the purchase, sale, lease, transfer or exchange of property or assets of any kind or the rendering of services of any kind) with any of its Affiliates, except any contract or agreement (a) set forth on <u>Schedule 6.19</u>, (b) with respect to any customary compensation and indemnification of, and other employment arrangement with, directors, officers and employees of Holdings or any of its Subsidiaries in the ordinary course of business or (c) any contract or agreement solely among one or more of Holdings and its Subsidiaries.

SECTION 6.20 <u>Investment Company Act</u>. None of Holdings, the Borrower or any Subsidiary is an "investment company" or is "controlled" by an "investment company," as such terms are defined in, or subject to regulation under, the Investment Company Act of 1940, as amended.

SECTION 6.21 OFAC. None of Holdings, the Borrower, any Subsidiary or, to the knowledge of the Borrower, any Related Party (a) is currently the subject of any Sanctions, (b) is located, organized or residing in any Designated Jurisdiction, or (c) is or has been (within the previous five years) engaged in any transaction with any Person who is now or was then the subject of Sanctions or who is located, organized or residing in any Designated Jurisdiction. No Loan, nor the proceeds from any Loan, has been or will be used, directly or, to the knowledge of the Borrower, indirectly, to lend, contribute or provide to, or has been or will be otherwise made available to fund, any activity or business in any Designated Jurisdiction or to fund any activity or business of any Person located, organized or residing in any Designated Jurisdiction or who is the subject of any Sanctions, or in any other manner that will result in any violation by any Person (including the Administrative Agent, any Lender and any of their respective Affiliates) of Sanctions.

SECTION 6.22 <u>Deposit and Disbursement Accounts</u>. Set forth on <u>Schedule 6.22</u> is a complete and accurate list as of the Closing Date of all banks and other financial institutions at which Holdings, the Borrower or any Subsidiary maintains deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts, such Schedule correctly identifies the name in which each such account is held, the type of each such account, and the complete account number for each such account, and each such account is a Controlled Account to the extent required pursuant to <u>Section 7.13</u>.

SECTION 6.23 <u>Customer and Trade Relations</u>. There exists no actual or, to the knowledge of the Borrower, threatened termination or cancellation of, or any material adverse modification or change in (a) the business relationship of Holdings, the Borrower or any Subsidiary with any customer or group of customers whose purchases during the preceding 12 calendar months caused such customer or group of customers to be ranked among the ten largest customers of Holdings, the Borrower or such Subsidiary, as applicable, or (b) the business relationship of Holdings, the Borrower or any Subsidiary with any supplier material to its operations.

SECTION 6.24 <u>Holdings</u>. Holdings is a passive holding company with no operations (other than such operations as are incidental to its status as a holding company), no assets (other than ownership of Capital Securities of the Borrower and such immaterial assets as are incidental to its status as a holding company), no liabilities (other than the Obligations under the Loan Documents, obligations under the Lender Warrants and such immaterial liabilities as are incidental to its status as a holding company) and no Subsidiaries (other than the Borrower).

ARTICLE VII AFFIRMATIVE COVENANTS

The Borrower covenants and agrees with the Administrative Agent and the Lenders that until the Termination Date has occurred, the Borrower will, and will cause Holdings and the Subsidiaries to, perform or cause to be performed the obligations set forth below.

SECTION 7.1 Financial Information, Reports, Notices, Etc. The Borrower will furnish the Administrative Agent and the Lenders copies of the following financial statements, reports, notices and information:

- (a) as soon as available and in any event within 30 days after the end of each calendar month (or solely with respect to any month ending on a Fiscal Quarter end on or before December 31, 2020, on or before the date that is five (5) Business Days after such 30-day period), in each case with supporting detail and certified as complete and correct by the chief financial or accounting Authorized Officer of the Borrower (subject to normal year-end audit adjustments), unaudited reports of (w) the Net Revenue for each Product for such calendar month and for the twelve-month period ending with the end of such calendar month, and including in comparative form the figures for the corresponding calendar month in the immediately preceding twelve-month period, (x) the Liquidity of the Borrower at the end of such calendar month and at the end of the corresponding calendar month in the preceding Fiscal Year, in comparative form, (y) the number of employees of Holdings, the Borrower and its Subsidiaries as of the end of such period, including any changes thereto and (z) prescription data of Holdings, the Borrower and its Subsidiaries with respect to each Product;
- (b) (i) as soon as available and in any event within 45 days after the end of each of the first three Fiscal Quarters of each Fiscal Year, an unaudited consolidated balance sheet of Holdings, the Borrower and the Subsidiaries as of the end of such Fiscal Quarter and consolidated statements of income and cash flow of Holdings, the Borrower and the Subsidiaries for such Fiscal Quarter and for the period commencing at the end of the previous Fiscal Year and ending with the end of such Fiscal Quarter and (ii) as soon as available and in any event within 45 days after the end of each Fiscal Quarter of each Fiscal Year, the Net Revenue for each Product for such Fiscal Quarter and for the twelve-month period ending with the end of such Fiscal Quarter, and including in comparative form the figures for the corresponding Fiscal Quarter in the immediately preceding twelve-month period, certified as complete and correct by the chief financial or accounting Authorized Officer of the Borrower (subject to normal year-end audit adjustments);
- (c) as soon as available and in any event within 120 days after the end of each Fiscal Year beginning with the Fiscal Year ended December 31, 2019, (i) a copy of the consolidated balance sheet of Holdings, the Borrower and the Subsidiaries, and the related consolidated statements of income, shareholders' equity and cash flow of Holdings, the Borrower and the Subsidiaries for such Fiscal Year, setting forth in comparative form the figures for the immediately preceding Fiscal Year, audited (without any Impermissible Qualification) by independent public accountants reasonably acceptable to the Required Lenders (it being understood that Deloitte & Touche LLP or any other "Big Four" accounting firm are reasonably acceptable to the Required Lenders) and (ii) the Net Revenue for each Product for such Fiscal Year and including in comparative form the figures for the immediately preceding Fiscal Year;

- (d) concurrently with the delivery of the financial information pursuant to <u>clauses (a)</u>, (b) and (c), a Compliance Certificate, executed by the chief financial or accounting Authorized Officer of the Borrower, and, in the case of a Compliance Certificate delivered concurrently with the delivery of the financial information pursuant to <u>clauses (b)</u> and (c), (i) showing compliance with the financial covenant set forth in <u>Section 8.4</u> and stating that no Event of Default has occurred and is continuing (or, if an Event of Default has occurred, specifying the details of such Event of Default and the action that Holdings, the Borrower or any of the Subsidiaries has taken or proposes to take with respect thereto), (ii) stating that no Subsidiary has been formed or acquired since the delivery of the last Compliance Certificate pursuant to <u>clause (b)</u> or (c) (or, if a Subsidiary has complied with <u>Section 7.8</u>) and (iii) stating that no real property has been acquired by Holdings, the Borrower or any of the Subsidiaries since the delivery of the last Compliance Certificate pursuant to <u>clause (b)</u> or (c) (or, if any real property has been acquired since the delivery of the last Compliance Certificate pursuant to <u>clause (b)</u> or (c), a statement that the Borrower has complied with <u>Section 7.8</u> with respect to such real property);
- (e) as soon as possible and in any event within five (5) Business Days after the Borrower obtains knowledge of the occurrence of an Event of Default, a statement of an Authorized Officer of the Borrower setting forth details of such Event of Default and the action which Holdings, the Borrower or any of the Subsidiaries has taken or proposes to take with respect thereto;
- (f) as soon as possible and in any event within five (5) Business Days after the Borrower obtains knowledge of (i) the occurrence of any material adverse development with respect to any litigation, action, proceeding or labor controversy described in <u>Schedule 6.7(a)</u> or (ii) the commencement of any litigation, action, proceeding or labor controversy of the type and materiality described in <u>Section 6.7</u>, notice thereof and, to the extent any Lender requests, copies of all documentation relating thereto;
- (g) as soon as possible and in any event within three days after the Borrower obtains knowledge of any (i) return related to any Product or inventory that involves more than \$3,000,000 or (ii) dispute or claim (other than matters subject to the preceding clause (i)) related to any Product or inventory that involves more than \$1,000,000;
- (h) as soon as possible and in any event within three days after the Borrower obtains knowledge of (i) any claim that Holdings, the Borrower, any of the Subsidiaries or one of their ERISA Affiliates has actual or potential liability in excess of \$1,000,000 under a Benefit Plan, (ii) any effort to unionize the employees of Holdings, the Borrower or any Subsidiary, or (iii) correspondence with the Internal Revenue Service regarding the qualification of a retirement plan under section 401(a) of the Code;

- (i) promptly after the sending or filing thereof, copies of all reports, notices, prospectuses and registration statements which Holdings, the Borrower or any of the Subsidiaries files with the SEC or any national securities exchange;
- (j) within five (5) Business Day of delivery thereof to the board of directors of Holdings and the Borrower or any committees thereof, copies of all written notices and any written materials delivered to the board of directors of Holdings and the Borrower or any committees thereof in connection with a meeting of such board or committee, or with any action to be taken by written consent, including drafts of any material resolutions or actions proposed to be adopted by written consent; <u>provided</u> that Holdings and the Borrower may withhold any such information and materials to the extent: (i) access thereto would adversely affect the attorney-client privilege between Holdings or the Borrower and its counsel; or (ii) the board of directors of Holdings or the Borrower, as applicable, in the exercise of its fiduciary obligations and with the advice of counsel, determines that (A) it is in the best interest of Holdings or the Borrower to do so because any Lender or any of its respective Affiliates has an interest in the subject matter under discussion, including discussions pertaining to this Agreement or the other Investment Documents or (B) doing so is necessary to discharge the directors' fiduciary duties;
- (k) promptly upon receipt thereof, copies of all "management letters" (or equivalent) submitted to Holdings, the Borrower or any of the Subsidiaries by the independent public accountants referred to in <u>clause (c)</u> in connection with each audit made by such accountants;
- (l) promptly upon receipt thereof, copies of all written subpoenas, requests for information and other notices regarding any active or potential investigation that could reasonably be expected to result in liabilities of \$1,000,000 (or its equivalent in another currency or currencies) or more or that is otherwise material of, or claim or litigation against, Holdings, the Borrower or any of the Subsidiaries by any Governmental Authority, and, except to the extent prohibited by Law or contract, the results of any inspections of any manufacturing facilities of Holdings, the Borrower or any of the Subsidiaries or any Third Party suppliers of Holdings, the Borrower or any of the Subsidiaries by any Governmental Authority (including any Form FDA 483s);
- (m) (i) within 45 days after the end of each Fiscal Quarter, a report listing (A) all Material Agreements and Key Contracts entered into during such Fiscal Quarter, (B) all existing Material Agreements or Key Contracts amended or terminated during such Fiscal Quarter and (C) all Permits, including all Regulatory Authorizations, issued to Holdings, the Borrower or any of the Subsidiaries during such Fiscal Quarter; and (ii) as soon as possible, and in any event within three days, after the Administrative Agent or any Lender so reasonably requests, copies of any such Material Agreement, Key Contract, amendment or termination instrument, Permit, Regulatory Authorization, notice or registration, in each case as are listed in such report;

- (n) [reserved];
- (o) as soon as possible and in any event within five (5) Business Days after receipt by, or delivery by, Holdings, the Borrower or any of the Subsidiaries, as the case may be, copies of any material written notice of material written correspondence relating to, or directly involving, any Key Contract, including any notice alleging breach or default under any Key Contract by any party thereto;
- (p) as soon as available, but in any event not later than March 31 of each Fiscal Year, the Borrower's financial and business projections and budget for such Fiscal Year, with reasonable evidence of approval thereof by the Borrower's board of directors; and
- (q) such other financial and other information as any Lender or the Administrative Agent may from time to time reasonably request (including information and reports in such detail as such Lender or the Administrative Agent may reasonably request with respect to the terms of and information provided pursuant to the Compliance Certificate).

SECTION 7.2 <u>Maintenance of Existence</u>; <u>Compliance with Contracts</u>, <u>Laws</u>, <u>Etc</u>. Except as would not reasonably be expected to result in a Material Adverse Effect, each of Holdings, the Borrower and each Subsidiary will (a) preserve and maintain its legal existence (except as otherwise permitted by <u>Section 8.7</u>), (b) perform in its obligations under Material Agreements and Key Contracts, in each case to which Holdings, the Borrower or any of the Subsidiaries is a party and (c) comply with all applicable Laws, rules, regulations and orders, including the payment (before the same become delinquent), of all Taxes, imposed upon Holdings, the Borrower or any of the Subsidiaries or upon their property except to the extent being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP have been set aside on the books of Holdings, the Borrower or any of the Subsidiaries, as applicable.

SECTION 7.3 <u>Maintenance of Properties</u>. Each of Holdings, the Borrower and the Subsidiaries will, in all material respects, maintain, preserve, protect and keep its and their respective material properties in good repair, working order and condition (ordinary wear and tear excepted), and make necessary repairs, renewals and replacements so that the business carried on by Holdings, the Borrower or any of the Subsidiaries may be properly conducted at all times, unless Holdings, the Borrower or any of the Subsidiaries determines in good faith that the continued maintenance of such property is no longer economically desirable, necessary or useful to the business of Holdings, the Borrower or any of the Subsidiaries or the Disposition of such property is otherwise permitted by <u>Section 8.7</u> or <u>Section 8.8</u>.

SECTION 7.4 Insurance. Each of Holdings, the Borrower and each of the Subsidiaries will maintain:

- (a) insurance on its property with financially sound and reputable insurance companies in at least the amounts (and with only those deductibles) and against such risks as are customarily maintained by Persons of comparable size engaged in the same or similar business and location as Holdings, the Borrower and the Subsidiaries; and
- (b) all worker's compensation, employer's liability insurance or similar insurance as may be required under the laws of any state or jurisdiction in which it may be engaged in business.

Without limiting the foregoing, the Borrower shall cause all insurance policies required pursuant to this Section to name the Administrative Agent as mortgagee and loss payee (in the case of property insurance) and additional insured (in the case of liability insurance), as applicable, and use commercially reasonable efforts to cause such insurance policies to provide that no cancellation or modification as to the amount or scope of coverage of the policies will be made without at least thirty (30) days' prior written notice (or ten (10) days' prior written notice in the case of the failure to pay any premiums thereunder) to Administrative Agent.

SECTION 7.5 <u>Books and Records</u>. Each of Holdings, the Borrower and each of the Subsidiaries will (a) keep books and records in accordance with GAAP which accurately reflect all of its business affairs and transactions, (b) permit the Administrative Agent, any Lender or any of their respective representatives, at reasonable times and intervals upon reasonable notice to the Borrower, to visit Holdings', the Borrower's or any of the Subsidiaries' financial or other matters with its officers and employees and to examine (and photocopy extracts from) any of its books and records and (c) use commercially reasonable efforts to permit the Administrative Agent, any Lender or any of their respective representatives, at reasonable times and intervals upon reasonable notice to the Borrower, to discuss financial or other matters with its independent public accountants. The Borrower shall pay any fees of such independent public accountant incurred in connection with the Administrative Agent's or any Lender's exercise of its rights pursuant to this Section.

SECTION 7.6 Environmental Law Covenant. Except as would not reasonably be expected to result in a Material Adverse Effect, each of Holdings, the Borrower and each of the Subsidiaries will (i) use and operate all of its and their businesses, facilities and properties in material compliance with all Environmental Laws, and keep and maintain all Environmental Permits and remain in compliance therewith, and (ii) promptly notify the Administrative Agent of, and provide the Administrative Agent with copies of all material claims, complaints, notices or inquiries relating to, any actual or alleged non-compliance with any Environmental Laws or Environmental Permits or any actual or alleged Environmental Liabilities. Holdings, the Borrower and each of the Subsidiaries will promptly resolve, remedy and mitigate any such non-compliance or Environmental Liabilities, and shall keep the Lenders informed as to the progress of same.

SECTION 7.7 [Reserved].

SECTION 7.8 Future Guarantors, Security, Etc. Holdings, the Borrower and each Subsidiary will execute any documents, financing statements, agreements and instruments, and take all further action that may be required under applicable law, or that the Administrative Agent or the Required Lenders may reasonably request, in order to effectuate the transactions contemplated by the Loan Documents and in order to grant, preserve, protect and perfect the validity and first priority (subject to Liens permitted by Section 8.3) of the Liens created or intended to be created by the Loan Documents. The Borrower will cause any subsequently acquired or organized Subsidiary to execute a supplement (in form and substance satisfactory to the Administrative Agent) to the Guarantee and each other applicable Loan Document in favor of the Secured Parties, effective upon its acquisition or formation. The Borrower will promptly notify the Administrative Agent of any subsequently acquired ownership interest in real property and will provide the Administrative Agent with a description of such real property, the acquisition date thereof and the purchase price therefor. In addition, from time to time, each of Holdings, the Borrower and each of the Subsidiaries will, at its cost and expense, promptly secure the Obligations by pledging or creating, or causing to be pledged or created, perfected Liens with respect to such of its assets and properties that constitute Collateral as the Administrative Agent or the Required Lenders shall designate, it being agreed that it is the intent of the parties that the Obligations shall be secured by substantially all of the assets of Holdings, the Borrower and the Subsidiaries (including owned real property and personal property acquired subsequent to the Closing Date) (with respect to any Subsidiary that is not a Foreign Subsidiary, subject to and in accordance with the limitations under the Security Agreement). Such Liens will be created under the Loan Documents in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders, and Holdings, the Borrower and each of the Subsidiaries shall deliver or cause to be delivered to the Administrative Agent all such instruments and documents (including mortgages, legal opinions, title insurance policies and lien searches) as the Administrative Agent or the Required Lenders shall reasonably request in writing to evidence compliance with this Section.

SECTION 7.9 <u>Obtaining of Permits, Etc.</u> With respect to Products, each of Holdings, the Borrower and each of the Subsidiaries will obtain, maintain and preserve, and take all necessary action to timely renew all material Permits which are necessary in the conduct of its business.

SECTION 7.10 <u>Post-Closing</u>. (a) Use commercially reasonable efforts to deliver (i) landlord access agreements in form and substance reasonably satisfactory to the Administrative Agent from each landlord to Holdings, the Borrower or any Subsidiary on the Closing Date and (ii) bailee letters in form and substance reasonably satisfactory to the Administrative Agent from (A) Integrated Commercialization Solutions, LLC and (B) Summit Access Solutions, LLC, dba RareMed Solutions and (b) deliver, no later than thirty (30) days following the Closing Date (or such later date as may be agreed to by the Administrative Agent, in its sole discretion), the insurance endorsements required under Section 7.4.

SECTION 7.11 Maintenance of Regulatory Authorizations, Contracts, Intellectual Property, Etc.

(a) With respect to the Products, each of Holdings, the Borrower and each of the Subsidiaries will (i) except as would not reasonably be expected to result in a Material Adverse Effect, maintain in full force and effect all Key Permits and contract rights, authorizations or other rights necessary for the operations of its business, including filing any notice or registration required in order to design, manufacture, store, label, sell, promote, import or distribute the Products; (ii) notify the Administrative Agent, promptly after learning thereof, of any material Product recalls, safety alerts, corrections, withdrawals, marketing suspensions, removals or the like conducted, to be undertaken or issued, by Holdings, the Borrower, any of the Subsidiaries or their respective suppliers whether or not at the request, demand or order of any Governmental Authority or otherwise with respect to any Product or manufacturing facility owned or operated by Holdings, the Borrower or any of the Subsidiaries, or any basis for undertaking or issuing any such action or item; (iii) except as would not reasonably be expected to result in a Material Adverse Effect, design, manufacture, store, label, sell, promote, import and distribute all Products in compliance with cGMPs, the FD&C Act, the PHSA, the Controlled Substances Act, and other applicable laws, rules and regulations; (iv) conduct all studies, tests and preclinical and clinical trials relating to the Products in accordance, in all material respects, with all cGCPs, and other applicable laws, rules and regulations; (v) operate and use commercially reasonable efforts to cause its suppliers to operate all manufacturing facilities in all material respects in compliance with cGMPs, the Controlled Substances Act, and all other applicable Laws, rules and regulations; (vi) maintain in full force and effect or pursue the prosecution of, as the case may be, and pay all costs and expenses relating to, all Owned Intellectual Property, all Key Contracts and all Material Agreements, except, in each case, in the event that the Borrower determines in its reasonable business judgment (as determined by the Borrower in good faith) not to do so; (vii) notify the Administrative Agent, reasonably promptly after obtaining knowledge thereof (and to the extent permitted by applicable Law), of any material Infringement or other material violation of any Owned Intellectual Property and pursue any such Infringement or other violation as Borrower determines in its reasonable commercial judgment; (viii) use commercially reasonable efforts, and subject to Borrower's reasonable business judgment, to pursue and maintain in full force and effect legal protection in all material respects for, and protect against material Infringement with respect to, all Owned Intellectual Property, including Patents; and (ix) notify the Administrative Agent, reasonably promptly after obtaining knowledge thereof (and to the extent permitted by applicable Law), of any material claim by any Person that the conduct of Holdings', the Borrower's or any of the Subsidiaries' business (including the development, manufacture, use, sale or other commercialization of any Product) Infringes any Intellectual Property of that Person and use commercially reasonable efforts to resolve such claim, except where the Borrower determines in its reasonable commercial judgment not to do so.

(b) Each of Holdings, the Borrower and its Subsidiaries will furnish to the Administrative Agent prompt written notice of the following, and, with respect to clauses

- (i) and (ii) below, copies of any material written notices from, or written responses to, the FDA or other Governmental Authority:
 - (i) any written notice that the FDA or other Governmental Authority is limiting, suspending or revoking any Key Permit, changing the market classification or labeling of or otherwise restricting in any material respect the Products of the Borrower or any of its Subsidiaries, or considering any of the foregoing;
 - (ii) Holdings, the Borrower or any of its Subsidiaries, or to the Borrower's knowledge any of its or their suppliers, becoming subject to any administrative or regulatory action, any FDA or EMA inspection, receipt of inspectional observations (e.g., on FDA Form 483), warning letter, untitled letter, or notice of violation letter, or any Product of the Borrower or any of its Subsidiaries being seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing or import alert, or the commencement of any proceedings in the United States or any other jurisdiction seeking the withdrawal, recall, suspension, import detention or refusal, or seizure of any Product are pending or, to Borrower's knowledge, threatened against the Borrower or any of its Subsidiaries; or
 - (iii) copies of any written recommendation from any Governmental Authority that Holdings, the Borrower or any of its Subsidiaries should have its licensure, provider or supplier number, or accreditation suspended, revoked, or limited in any way, or any penalties or sanctions imposed.

SECTION 7.12 Inbound Licenses. Each of Holdings, the Borrower and the Subsidiaries will, promptly after entering into or becoming bound by any inbound license or agreement for Intellectual Property (other than over-the-counter or "open-source" software that is commercially available to the public, or non-exclusive immaterial license entered into in the ordinary course of business) (i) provide written notice to the Administrative Agent of the material terms of such license or agreement with a description of its anticipated and projected impact on Holdings, the Borrower's and the Subsidiaries' business and financial condition; and (ii) except to the extent that the Borrower determines in its reasonable commercial judgment that it is not in the best interest of Holdings, the Borrower or the Subsidiaries to do so, take such commercially reasonable actions as the Administrative Agent or the Required Lenders may reasonably request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for the Secured Parties to be granted and perfect a valid security interest in such license or agreement and to fully exercise its rights under any of the Loan Documents in the event of a disposition or liquidation of the rights, assets or property that is the subject of such license or agreement.

SECTION 7.13 Cash Management. Each of Holdings, the Borrower and the Subsidiaries will:

- (a) maintain a current and complete list of all accounts (of the type initially set forth on Schedule 6.22) and (other than accounts (i) exclusively used for payroll, payroll taxes and other employee wage and benefit programs to or for the benefit of Holdings', the Borrower's or a Subsidiary's employees, which shall in no event hold in the aggregate more than the amount reasonably expected to meet such payroll expenses for the following calendar month, including bonuses and other payments to be paid within the following calendar month, (ii) exclusively used for the receipt of receivables solely funded by Medicare or Medicaid, which shall in no event hold in the aggregate more than \$5,000 and whose total cash balances shall be automatically swept to a Controlled Account (as defined below), on at least a monthly basis, (iii) exclusively used to hold cash or Cash Equivalents that serves as collateral or security permitted under Section 8.3(g), (h), (m), (o), (p) or (q) whereby the applicable secured party prohibits the creation of a Lien on such account in favor of Administrative Agent, (iv) located in a jurisdiction other than the United States, any state, territory or municipality thereof or the District of Columbia where an account control agreement or similar agreement is not required for the perfection of a security interest in such account under the applicable Law of such jurisdiction and (v) with balances or assets which do not exceed \$1,000,000 in the aggregate at any one time (collectively, the "Excluded Accounts")) promptly deliver any updates to such list to the Administrative Agent; execute and maintain an account control agreement for each such account (other than the Excluded Accounts), in form and substance reasonably acceptable to the Administrative Agent (each such account, a "Controlled Account"); and
- (b) deposit promptly after the date of receipt thereof in accordance with prudent business practices all cash, checks, drafts or other similar items of payment relating to or constituting payments made in respect of any and all accounts and other rights and interests into Controlled Accounts except to the extent permitted to be kept in Excluded Accounts.

SECTION 7.14 <u>Lender Meetings</u>. To the extent requested by the Administrative Agent no more frequently than once per Fiscal Quarter, the Chief Executive Officer of the Borrower shall participate in a telephonic conference call with the Lenders at such time as may be agreed upon by the Borrower and the Administrative Agent.

ARTICLE VIII NEGATIVE COVENANTS

The Borrower covenants and agrees with the Administrative Agent and the Lenders that until the Termination Date has occurred, Holdings, the Borrower and the Subsidiaries will perform or cause to be performed the obligations set forth below.

SECTION 8.1 <u>Business Activities</u>. None of Holdings, the Borrower or any of the Subsidiaries will engage in any business activity except those business activities engaged in on the date of this Agreement and activities reasonably incidental thereto.

SECTION 8.2 <u>Indebtedness</u>. None of Holdings, the Borrower or any of the Subsidiaries will create, incur, assume or permit to exist any Indebtedness, other than:

- (a) Indebtedness in respect of the Obligations;
- (b) until the Closing Date, Indebtedness that is to be repaid in full as further identified in <u>Schedule 8.2(b)</u>;
- (c) Indebtedness existing as of the Closing Date which is identified in Schedule 8.2(c), and Permitted Refinancings thereof;
- (d) unsecured Indebtedness in respect of performance, stay, customs, surety or appeal bonds provided in the ordinary course of business;
- (e) Purchase Money Indebtedness and Capitalized Lease Liabilities (excluding any Indebtedness permitted in reliance on <u>Section</u> <u>8.2(j)</u>) in a principal amount not to exceed \$2,000,000 in the aggregate outstanding at any time;
 - (f) Permitted Subordinated Indebtedness;
 - (g) Indebtedness of Holdings, any Subsidiary or the Borrower owing to Holdings, the Borrower or any Subsidiary;
- (h) letters of credit and banker's acceptances issued on behalf of Holdings, the Borrower or any Subsidiary in the ordinary course of business;
- (i) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by Holdings, the Borrower or any Subsidiary in the ordinary course of business;
- (j) Capitalized Lease Liabilities that constitute automobile leases in a principal amount not to exceed \$3,500,000 in the aggregate outstanding at any time;
- (k) Indebtedness incurred in connection with corporate credit cards in an aggregate principal amount at any time outstanding not to exceed \$2,000,000;
- (l) cash management obligations and other Indebtedness in respect of netting services, overdraft protections and similar arrangements and Indebtedness arising from the honoring by a bank or other financial institution of a check, draft or similar instrument drawn against insufficient funds in the ordinary course of business;
 - (m) Indebtedness consisting of financing of insurance premiums;
- (n) Indebtedness in respect of earnouts and other similar contingent obligations, in each case, incurred in connection with a Permitted Acquisition or the LatAm Transaction;

- (o) customary indemnification obligations in favor of purchasers in connection with Dispositions permitted hereunder;
- (p) obligations in respect of customary working capital adjustment requirements in connection with any Permitted Acquisition, the LatAm Transaction or any other Investment permitted hereunder;
- (q) Indebtedness consisting of promissory notes issued to former officers, directors, employees, members of management or consultants (or their respective estates, heirs, family members, spouses, former spouses, domestics partners or former domestic partners) to finance the purchase or redemption of Capital Securities of Holdings or any direct or indirect parent of Holdings permitted by Section 8.6;
 - (r) [reserved];
- (s) Indebtedness in respect of obligations arising under a Hedging Agreements entered into in the ordinary course of Holdings' financial planning solely to hedge currency and interest rate risks (and not for speculative purposes)
 - (t) to the extent constituting Indebtedness, any obligations arising under the Lender Warrants; and
- (u) other Indebtedness of Holdings, the Borrower and the Subsidiaries in an aggregate amount at any time outstanding not to exceed \$2,000,000;

provided that no Indebtedness otherwise permitted by <u>clauses (f)</u> or <u>(n)</u> shall be assumed, created or otherwise incurred on or after the date any Event of Default first occurred until such Event of Default is no longer continuing or at any time that an Event of Default would result from such assumption creation or incurrence.

SECTION 8.3 <u>Liens</u>. None of Holdings, the Borrower or any of the Subsidiaries will create, incur, assume or permit to exist any Lien upon any of its property (including Capital Securities of any Person), revenues or assets, whether now owned or hereafter acquired, except:

- (a) Liens securing payment of the Obligations;
- (b) until the Closing Date, Liens securing payment of Indebtedness of the type described in clause (b) of Section 8.2;
- (c) Liens existing as of the Closing Date and disclosed in <u>Schedule 8.3(c)</u> securing Indebtedness described in <u>clause (c)</u> of <u>Section 8.2</u>, and Permitted Refinancings of such Indebtedness; <u>provided</u> that, no such Lien shall encumber any additional property and the amount of Indebtedness secured by such Lien is not increased from that existing on the Closing Date or any Permitted Refinancings thereof;

- (d) Liens securing payment of Permitted Subordinated Indebtedness that are (i) subordinate to the Liens securing payment of the Obligations and all other Indebtedness owing from Holdings, the Borrower or the Subsidiaries to the Secured Parties and (ii) subject to a written subordination agreement satisfactory to the Secured Parties in their sole discretion;
- (e) Liens securing Indebtedness of Holdings, the Borrower or the Subsidiaries permitted pursuant to <u>Sections 8.2(e)</u> or <u>(j)</u> (<u>provided</u> that (i) such Liens shall be created within 180 days of the acquisition or lease of the assets financed with such Indebtedness and (ii) such Liens do not at any time encumber any property other than the property so financed and the proceeds thereof);
- (f) Liens in favor of carriers, warehousemen, mechanics, materialmen and landlords granted in the ordinary course of business (x) which do not in the aggregate materially detract from the value of the Property subject thereto or materially impair the use thereof in the operations of the business of such Person or (y) for amounts not overdue or being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP shall have been set aside on its books;
- (g) Liens incurred or deposits made in the ordinary course of business in connection with worker's compensation, unemployment insurance or other forms of governmental insurance or benefits, or to secure performance of tenders, statutory obligations, bids, leases or other similar obligations (other than for borrowed money) entered into in the ordinary course of business or to secure obligations on surety and appeal bonds or performance bonds;
 - (h) Liens securing judgments which do not result in an Event of Default under Section 9.1(f);
- (i) easements, rights-of-way, zoning restrictions, minor defects or irregularities in title and other similar encumbrances not interfering in any material respect with the value or use of the property to which such Lien is attached;
- (j) Liens for Taxes not at the time delinquent or thereafter payable without penalty or being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP shall have been set aside on its books;
- (k) non-exclusive (other than with respect to territories or regions outside of the United States or in connection with licenses granted with respect to specific states or regions in the United States solely in connection with customary manufacturing arrangements) licenses and/or sublicenses of Intellectual Property entered into in the ordinary course of business;
 - (l) Liens on insurance policies and the proceeds thereof securing the financing of the premiums with respect thereto;

- (m) Liens and cash deposits for obligations of landlords and sublandlords and in connection with any obligations and Indebtedness permitted by <u>Section 8.2(h)</u>;
- (n) Leases and subleases granted to others in the ordinary course of business which do not interfere in any material respect with the business of Holdings, the Borrower and the Subsidiaries;
- (o) Liens on specific items of inventory or other goods and proceeds thereof of any Person securing such Person's obligations in respect of bankers' acceptances or letters of credit issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or such goods or products in the ordinary course of business;
- (p) Liens (i) on cash advances in favor of the seller of any property to be acquired in an Investment or other acquisition permitted pursuant to this Agreement or any other Loan Document to be applied against the purchase price for such Investment or other acquisition or (ii) on the escrowed cash portion of any earnest moneys paid or the purchase price received in connection with any Investment, acquisition or Disposition permitted by this Agreement or any other Loan Document to secure guarantees, indemnities, or obligations in an aggregate principal amount at any time outstanding not to exceed \$1,000,000 in respect of earnouts or other purchase price adjustments or similar obligations incurred in connection with such Investment, acquisition or Disposition;
- (q) Liens solely on any cash earnest money deposits made by any Holdings, the Borrower or any Subsidiaries in connection with any letter of intent or purchase agreement permitted under this Agreement or any other Loan Document;
- (r) Liens arising out of conditional sale, title retention, consignment or similar arrangements for sale of goods or products entered into by Holdings, the Borrower or any Subsidiary in the ordinary course of business;
- (s) Liens arising from precautionary UCC financing statement or similar filings regarding operating leases entered into in the ordinary course of business;
 - (t) any condemnation or eminent domain proceedings affecting any real property;
- (u) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Holdings', the Borrower's or any Subsidiary's deposit accounts or securities accounts held at such institutions to secure solely payment of fees and similar costs and expenses; <u>provided</u> such accounts are maintained in compliance with <u>Section 7.13(a)</u>; and
- (v) other Liens on assets securing Indebtedness or other obligations in an aggregate principal amount at any time outstanding not to exceed \$2,000,000.

Each Secured Party agrees to execute and deliver such collateral subordination agreements and related documents as reasonably requested of it to confirm the priority of the Liens permitted pursuant to <u>clause (e)</u> of <u>Section 8.3.</u>

SECTION 8.4 Minimum Liquidity. The Liquidity of the Borrower shall not at any time be less than \$12,500,000.

SECTION 8.5 <u>Investments</u>. None of Holdings, the Borrower or any of the Subsidiaries will purchase, make, incur, assume or permit to exist any Investment in any other Person, except:

- (a) Investments existing on the Closing Date and identified in Schedule 8.5(a);
- (b) (x) Cash Equivalent Investments and (y) Investments consisting of deposit accounts and securities accounts maintained in accordance with the terms of this Agreement and the other Loan Documents containing cash and such Cash Equivalent Investments;
- (c) Investments received in connection with the bankruptcy or reorganization of, or settlement of delinquent accounts and disputes with, customers and suppliers, in each case in the ordinary course of business;
- (d) Investments consisting of any deferred portion of the sales price received by Holdings, the Borrower or any of the Subsidiaries in connection with any Disposition permitted under <u>Section 8.8</u>;
- (e) Investments constituting (i) accounts receivable arising, (ii) trade debt granted, or (iii) deposits made, in each case of <u>clauses</u> (<u>i)</u> through (<u>iii)</u> in connection with the purchase price of goods or services, in each case in the ordinary course of business;
 - (f) Permitted Acquisitions and the LatAm Transaction;
 - (g) Investments by the Borrower or any Guarantor in the Borrower or any Guarantor;
- (h) Hedging Agreements entered into in the ordinary course of financial planning solely to hedge currency and interest rate risks (and not for speculative purposes);
- (i) employee loans, travel advances and guarantees in accordance with usual and customary practices with respect thereto (if permitted by applicable law) which in the aggregate shall not exceed \$500,000 outstanding at any time;
- (j) Investments consisting of promissory notes issued by officers, directors and employees the proceeds of which are used by such Persons to simultaneously purchase Capital Securities of Holdings or its direct or indirect equity holders;

- (k) advances of payroll payments to employees and consultants in the ordinary course of business;
- (l) Investments (other than Acquisitions) to the extent that payment for such Investments is made solely with issuances of Qualified Capital Securities of Holdings (or any direct or indirect parent thereof) issued on or up to sixty (60) days prior to the date of consummation of such transaction and not used to consummate Permitted Acquisitions so long as EBITDA, calculated both before, and on a pro forma basis after, giving effect to such Investment, is no less than \$10,000,000; and
 - (m) other Investments in an aggregate amount not to exceed \$2,000,000 over the term of this Agreement.

SECTION 8.6 <u>Restricted Payments</u>, <u>Etc.</u> None of Holdings, the Borrower or any of the Subsidiaries will declare or make a Restricted Payment, or make any deposit for any Restricted Payment, other than:

- (a) Restricted Payments made by the Borrower or Subsidiaries to Holdings, the Borrower or any Subsidiaries;
- (b) Holdings may declare and pay dividends with respect to its capital stock and its Capital Securities payable solely in additional shares of its common stock and its Qualified Capital Securities (other than any common stock or other Qualified Capital Securities constituting tracking stock);
- (c) Holdings may make Restricted Payments pursuant to and in accordance with restricted stock agreements, stock option plans or other benefit plans for management, directors or employees of Holdings and its Subsidiaries in an aggregate amount not to exceed \$250,000 in any Fiscal Year;
- (d) Holdings may make Restricted Payments for the purpose of redeeming from former directors, officers, employees, members of management, managers or consultants of Holdings, Borrower or any Subsidiary (or their respective family members, former spouses or estate) Capital Securities of Holdings or its direct or indirect parent Persons (and/or making payments on promissory notes issued by Holdings or its Subsidiaries pursuant to Section 8.2) and any tax payments related thereto, so long as the Borrower, after giving effect to such Restricted Payment, is in compliance with the covenant set forth in Section 8.4;
- (e) Holdings may make repurchases of Capital Securities deemed to occur upon the cash-less or net exercise of stock options, warrants or other convertible or exchangeable securities;
- (f) Holdings may make repurchases of Capital Securities deemed to occur upon the withholding of a portion of the Capital Securities granted or awarded to a current or former officer, director, employee or consultant to pay for the taxes payable by such Person upon such grant or award (or upon vesting or exercise thereof);

- (g) Holdings may pay cash in lieu of the issuance of fractional shares by Holdings or any of its direct or indirect parent Persons, in an aggregate amount not to exceed \$100,000;
- (h) to the extent such payments would constitute Restricted Payments, so long as no Event of Default has occurred and is continuing or would immediately result after giving effect thereto, Borrower may make payments to Paragon that are required to be made pursuant to any Paragon Management Agreement; provided that (i) any such payments prohibited due to the occurrence and continuance of an Event of Default may be accrued and subsequently paid at any time so long as no Event of Default has occurred and is continuing or would immediately result from such payment and (ii) indemnities or expense reimbursements that are required to be paid under any Paragon Management Agreement may be made notwithstanding the occurrence and continuation of an Event of Default; and
- (i) Holdings may declare or make, or agree to pay or make Restricted Payments which are contingent upon either (i) the prior consent of Administrative Agent or the Required Lenders or (ii) the repayment in full of the Obligations (other than contingent indemnification and expense reimbursement obligations for which no claims have been made) and the termination of the Commitments.

SECTION 8.7 <u>Consolidation, Merger; Permitted Acquisitions, LatAm Transaction, Etc.</u> (a) None of Holdings, the Borrower or any of the Subsidiaries will liquidate or dissolve, consolidate with, or merge into or with, any other Person, or (b) purchase or otherwise acquire all or substantially all of the assets of any Person (or any division, business unit or line of business thereof, including any geographic subset thereof), including through an exclusive lease or license, other than in the case of clause (b) to consummate a Permitted Acquisition, the LatAm Transaction or a Disposition permitted under <u>Section 8.8</u>, except that, in the case of each of clauses (a) and (b), so long as no Event of Default has occurred and is continuing (or would occur), any Subsidiary may liquidate or dissolve voluntarily into, and may merge with and into, Holdings, the Borrower or any Subsidiary; and <u>provided</u> that, in connection with any Permitted Acquisition, the Borrower or any Subsidiary of the Borrower may merge into or consolidate with any other Person or permit any other Person to merge into or consolidate with it, so long as (i) the Person surviving such merger with any Subsidiary shall be a direct or indirect wholly owned Subsidiary of the Borrower and a Guarantor, and (ii) in the case of any such merger to which the Borrower is a party, the Borrower is the surviving Person.

SECTION 8.8 <u>Permitted Dispositions</u>. None of Holdings, the Borrower or any of the Subsidiaries will Dispose of any of its assets (including accounts receivable of Holdings, the Borrower or Subsidiaries) to any Person in one transaction or series of transactions, except as follows:

(a) Dispositions of inventory or obsolete, damaged, worn out or surplus property in the ordinary course of its business;

- (b) transfers of cash and Cash Equivalent Investments in the ordinary course of business for equivalent value;
- (c) non-exclusive (other than with respect to territories or regions outside of the United States or in connection with licenses granted with respect to specific states or regions in the United States solely in connection with customary manufacturing arrangements) licenses and non-exclusive (other than with respect to territories or regions outside of the United States or in connection with licenses granted with respect to specific states or regions in the United States solely in connection with customary manufacturing arrangements) sublicenses of Intellectual Property, in each case entered into in the ordinary course of business;
- (d) leases and subleases of real property and other property (other than Intellectual Property) and licenses or sublicenses of personal property (other than Intellectual Property) to third parties in the ordinary course of business, in each case, not interfering with the material business of the Borrower or Guarantors;
- (e) the lapse, abandonment, cancellation or other Disposition of Intellectual Property that is, in the good faith judgment of the Borrower or a Guarantor, no longer economically practicable or commercially desirable to maintain or useful in the conduct of the business of the Borrower or such Guarantor;
- (f) the sale, forgiveness or discounting, in each case without recourse and in the ordinary course of business, of accounts receivable in connection with resolving any dispute relating thereto or in connection with the bankruptcy or reorganization of suppliers or customers;
- (g) the sale, transfer, disposition or other Disposition of the Capital Securities of any Foreign Subsidiary to qualified directors where required by applicable Laws;
- (h) Dispositions to landlords of improvements made to leased real property pursuant to customary terms of leases entered into in the ordinary course of business;
- (i) Dispositions of equipment in the ordinary course of business to the extent that (x) such equipment is exchanged for credit against the purchase price of similar replacement equipment or (y) the proceeds of such Disposition are promptly applied to the purchase price of such replacement equipment;
 - (j) the unwinding of any Hedging Agreement or similar arrangement;
- (k) the exercise by the Borrower, Holdings or any Subsidiary of termination rights under any lease, sublease, license, sublicense, concession or other agreements;

(l) any other Disposition in an aggregate amount not to exceed \$1,000,000; <u>provided</u> that (i) at least 75% of the consideration received in such Disposition is in the form of cash or Cash Equivalent Investments (it being understood and agreed that any contingent or deferred consideration payable in cash or Cash Equivalent Investments shall be excluded from the calculation of whether 75% of the consideration is in the form of cash or Cash Equivalent Investments), and (ii) the consideration received is at least equal to the fair market value of the property Disposed of

- (m) any licenses or sublicenses constituting part of the LatAm Transaction; and
- (n) Dispositions of property as a result of a Casualty Event.

SECTION 8.9 <u>Modification of Certain Agreements</u>. None of Holdings, the Borrower or any of the Subsidiaries will consent to any amendment, supplement, waiver or other modification of, or enter into any forbearance from exercising any rights with respect to, the terms or provisions contained in (a) any Organic Documents of Holdings, the Borrower or any of the Subsidiaries, if the result would have a material adverse effect on the rights or remedies of the Administrative Agent or the Lenders under this Agreement or any Investment Document, (b) any agreement governing any Permitted Subordinated Indebtedness, if the result would shorten the maturity date thereof or advance the date on which any cash payment is required to be made thereon or would otherwise change any terms thereof in a manner adverse to the Administrative Agent or the Lenders (unless otherwise permitted by the applicable subordination agreement) or (c) any Key Contract, if the result could reasonably be expected to have a material and adverse effect on the Administrative Agent or the Lenders. Other than in a transaction contemplated under Section 8.3(a) or (k) or Section 8.8(c) or (m) (including, in each case, any transfer of obligations in connection therewith) and solely to the extent that Holdings, the Borrower or a Subsidiary has an express contractual consent or approval right under a Designated Key Contract with respect to, or would otherwise be required to consent to or approve such transaction for it to be effective, the assignment or transfer of such Designated Key Contract, or any material rights or obligations thereunder, by a party thereto, none of Holdings, the Borrower or such Subsidiary will agree to any such assignment or transfer by such party.

SECTION 8.10 <u>Transactions with Affiliates</u>. None of Holdings, the Borrower or any of the Subsidiaries will enter into or cause or permit to exist any arrangement, transaction or contract (including for the purchase, lease or exchange of property or the rendering of services) with any of its Affiliates (other than Holdings, the Borrower or any Subsidiary), unless such arrangement, transaction or contract (i) is on fair and reasonable terms no less favorable to Holdings, the Borrower or any Subsidiary than it could obtain in an arm's-length transaction with a Person that is not one of its Affiliates, (ii) is the customary compensation and indemnification of, and other employment arrangement with, directors, officers and employees of Holdings or any of its Subsidiaries in the ordinary course of business, (iii) the transactions set forth on

Schedule 8.10 (and any amendment thereto or replacement thereof to the extent such an amendment or replacement is not materially adverse to the Lenders), (iv) is among Holdings, the Borrower and/or one or more of its direct or indirect shareholders, solely in their respective capacities as holders of the Capital Securities of Holdings, including, without limitation, agreements with respect to the issuances thereof and investment agreements, (v) is a Restricted Payment permitted under Section 8.6 or (vi) is of the kind which would be entered into by a prudent Person in its position with a Person that is not one of its Affiliates.

SECTION 8.11 Restrictive Agreements, Etc. None of Holdings, the Borrower or any of the Subsidiaries will enter into any agreement prohibiting (x) the creation or assumption of any Lien upon its properties, revenues or assets, whether now owned or hereafter acquired, in favor of the Administrative Agent and the Secured Parties, or (y) the ability of Holdings, the Borrower or any Subsidiary to make any payments, directly or indirectly, to the Borrower, including by way of dividends, advances, repayments of loans, reimbursements of management and other intercompany charges, expenses and accruals or other returns on investments. The foregoing prohibitions shall not apply to (a) restrictions contained in any Investment Document, (b) in the case of clause (x), (i) restrictions contained in any agreement governing any Indebtedness permitted by clauses (e) or (j) of Section 8.2 as to the assets financed with the proceeds of such Indebtedness, (ii) prohibitions, restrictions and conditions imposed by Requirements of Law and (iii) customary provisions in contracts (including leases, subleases, licenses and sublicenses of Intellectual Property and/or other property) restricting the assignment thereof and (c) in the case of clause (y), (i) those imposed by Requirements of Law and (ii) prohibitions, restrictions and conditions contained in any agreement or document relating to the consummation of a transaction which is conditioned upon (A) the amendment, restatement, modification or replacement of this Agreement which would have the effect of consenting to such prohibition, restriction or condition or (B) the repayment in full (other than contingent indemnification and expense reimbursement obligations for which no claim has been made) of Obligations owing under this Agreement and the termination of the Commitments.

SECTION 8.12 <u>Sale and Leaseback</u>. None of Holdings, the Borrower or any of the Subsidiaries will directly or indirectly enter into any agreement or arrangement providing for the sale or transfer by it of any property (now owned or hereafter acquired) to a Person and the subsequent lease or rental of such property or other similar property from such Person.

SECTION 8.13 <u>Product Agreements</u>. None of Holdings, the Borrower or any of the Subsidiaries will enter into any amendment with respect to any existing Product Agreement or enter into any new Product Agreement (other than any Product Agreement related to the LatAm Transaction) that contains any provision that permits any counterparty other than Holdings, the Borrower or any of the Subsidiaries to terminate such Product Agreement for any reason related to the insolvency or change of control of Holdings, the Borrower or any of the Subsidiaries or assignment of such Product Agreement by Holdings, the Borrower or any of the Subsidiaries.

SECTION 8.14 Change in Name, Location or Executive Office or Executive Management; Change in Fiscal Year. None of Holdings, the Borrower or any of the Subsidiaries will (i) change its legal name or any trade name used to identify it in the conduct of its business or ownership of its properties, (ii) change its jurisdiction of organization or legal structure (other than the conversion of the Borrower from a Delaware limited liability company to a Delaware corporation in connection with a Qualified IPO), (iii) relocate its chief executive office, principal place of business or any office in which it maintains books or records relating to its business (including the establishment of any new office or facility), (iv) change its federal taxpayer identification number or organizational number (or equivalent) or (v) replace its chief executive officer or chief financial officer, in the case of each of clauses (i) and (iii) through (v), without written notification to the Administrative Agent within 30 days thereafter. None of Holdings, the Borrower or any of the Subsidiaries will (x) change its Fiscal Year or any of its Fiscal Quarters or (y) enter into any Division/Series Transaction, or permit any of its Subsidiaries to enter into, any Division/Series Transaction (it being understood that none of the provisions in this Agreement nor any other Investment Document shall be deemed to permit any Division/Series Transaction).

SECTION 8.15 Benefit Plans and Agreements. Except as would not reasonably be expected to result in a Material Adverse Effect, none of Holdings, the Borrower or any Subsidiary will (i) become the sponsor of, incur any responsibility to contribute to or otherwise incur actual or potential liability with respect to, any Benefit Plan, (ii) allow any "employee benefit plan" as defined in section 3(3) of ERISA that provides retirement benefits, is sponsored by Holdings, the Borrower, any Subsidiary or any of their ERISA Affiliates, and is intended to be tax qualified under section 401 of the Code to cease to be tax qualified, (iii) allow the assets of any tax qualified retirement plan to become invested in Capital Securities of Holdings, the Borrower or any Subsidiary, or (iv) allow any employee benefit plan, program or arrangement sponsored, maintained, contributed to or required to be contributed to by Holdings, the Borrower or any Subsidiary to fail to comply in all material respects with its terms and applicable law.

SECTION 8.16 <u>Holdings</u>. Holdings shall not have any operations (other than such operations as are incidental to its status as a holding company), own any assets (other than ownership of Capital Securities of the Borrower and such immaterial assets as are incidental to its status as a holding company), incur any liabilities (other than the Obligations under the Loan Documents, obligations under the Lender Warrants and such immaterial liabilities as are incidental to its status as a holding company) or form any Subsidiaries; <u>provided</u> that Holdings may engage in transactions it is expressly authorized to undertake under the terms of this <u>Article VIII</u>.

SECTION 8.17 <u>Use of Proceeds</u>. The Borrower shall not use the proceeds of the Loans for any purpose other than (a) for general working capital purposes and corporate purposes, including, without limitation, the payment of any milestone payments required under the Key Contracts and expenditures made in support of the U.S. commercialization of the Product, (b) to finance of any Permitted Acquisition, the

LatAm Transaction or other Investment permitted hereunder, including the payment of any fees, costs and expenses incurred in connection therewith, (c) to fund the Existing Debt Refinancing and pay any fees, costs or expenses incurred in connection therewith and (d) to pay fees, costs and expenses incurred in connection with the execution, delivery and performance of this Agreement and the other Investment Documents.

ARTICLE IX EVENTS OF DEFAULT

SECTION 9.1 <u>Listing of Events of Default</u>. Each of the following events or occurrences described in this <u>Article IX</u> shall constitute an "<u>Event of Default</u>".

- (a) <u>Non-Payment of Obligations</u>. The Borrower shall default in the payment or prepayment when due of (i) any principal of any Loan, or (ii) any interest on any Loan or any fee described in <u>Article III</u> or any other monetary Obligation, and in the case of <u>clause (ii)</u> such default shall continue unremedied for a period of three (3) Business Days after such amount was due.
- (b) <u>Breach of Warranty</u>. Any representation or warranty made or deemed to be made by Holdings, the Borrower or any of the Subsidiaries in any Loan Document (including any certificates delivered pursuant to <u>Article V</u>) is or shall be incorrect in any material respect when made or deemed to have been made.
- (c) Non-Performance of Certain Covenants and Obligations. Holdings, the Borrower or any Subsidiary shall default in the due performance or observance of any of its obligations under $\underline{\text{Sections } 7.1(\underline{a})} \underline{(e)}$ or $\underline{\text{Article VIII}}$.
- (d) Non-Performance of Other Covenants and Obligations. Holdings, the Borrower or any Subsidiary shall default in the due performance and observance of any other covenant, obligation or agreement contained in any Loan Document executed by it, and such default shall continue unremedied for a period of 30 days after the earlier to occur of (i) notice thereof given to the Borrower by the Lenders or (ii) the date on which Holdings, the Borrower or any Subsidiary has knowledge of such default.
- (e) <u>Default on Other Indebtedness</u>. A default shall occur in the payment of any amount when due (subject to any applicable grace period), whether by acceleration or otherwise, of any principal or stated amount of, or interest or fees on, any Indebtedness of Holdings, the Borrower or any of the Subsidiaries having a principal or stated amount, individually or in the aggregate, in excess of \$2,000,000, or a default shall occur in the performance or observance of any obligation or condition with respect to such Indebtedness if the effect of such default is to accelerate the maturity of any such Indebtedness or such default shall continue unremedied for any applicable period of time sufficient to permit the holder or holders of such Indebtedness, or any trustee or agent for such holders, to cause or declare such Indebtedness to become due and payable or to require such Indebtedness to be prepaid, redeemed, purchased or defeased, or require an offer to purchase or

defease such Indebtedness to be made, prior to its expressed maturity; <u>provided</u> that any Default or Event of Default under this <u>Section 9.1(e)</u> caused by such default shall be automatically waived and cured under this Agreement and the other Loan Documents without any action on the part of any Secured Party immediately following the waiver and/or cure of such default under such agreement, instrument or document governing or evidencing such Indebtedness.

- (f) <u>Judgments</u>. Any judgment or order for the payment of money individually or in the aggregate in excess of \$2,000,000 (exclusive of any amounts fully covered by insurance (less any applicable deductible) and as to which the insurer has acknowledged its responsibility to cover such judgment or order) shall be rendered against Holdings, the Borrower or any of the Subsidiaries and such judgment shall not have been vacated or discharged or stayed or bonded pending appeal within sixty (60) days after the entry thereof or enforcement proceedings shall have been commenced by any creditor upon such judgment or order.
 - (g) Change in Control. Any Change in Control shall occur.
 - (h) Bankruptcy, Insolvency, Etc. Holdings, the Borrower or (except as permitted pursuant to Section 8.7) any of the Subsidiaries shall
 - (i) become insolvent or generally fail to pay, or admit in writing its inability or unwillingness generally to pay, debts as they become due;
 - (ii) apply for, consent to, or acquiesce in the appointment of a trustee, receiver, sequestrator or other custodian for any substantial part of the property of any thereof, or make a general assignment for the benefit of creditors;
 - (iii) in the absence of such application, consent or acquiescence in or permit or suffer to exist the appointment of a trustee, receiver, sequestrator or other custodian for a substantial part of the property of any thereof, and such trustee, receiver, sequestrator or other custodian shall not be discharged within 60 days; <u>provided</u> that, Holdings, the Borrower and each Subsidiary hereby expressly authorizes the Administrative Agent and the Lenders to appear in any court conducting any relevant proceeding during such 60-day period to preserve, protect and defend its rights under the Investment Documents;
 - (iv) permit or suffer to exist the commencement of any bankruptcy, insolvency, reorganization, debt arrangement, arrangement (including any plan of compromise or arrangement or other corporate proceeding involving or affecting its creditors) or other case or proceeding under any bankruptcy or insolvency law or any dissolution, winding up or liquidation proceeding, in respect thereof (each, an "Insolvency Event"), and, if any such case or proceeding is not commenced by Holdings, the Borrower or any Subsidiary, such case or proceeding shall be consented to or acquiesced in by Holdings, the Borrower or such Subsidiary, as the case may be, or shall result in the entry of an order for relief or shall remain for 60 days undismissed; provided that Holdings, the Borrower and each

Subsidiary hereby expressly authorizes the Administrative Agent and the Lenders to appear in any court conducting any such case or proceeding during such 60-day period to preserve, protect and defend its rights under the Investment Documents; or

- (v) take any action authorizing, or in furtherance of, any of the foregoing.
- (i) <u>Impairment of Security, Etc.</u> Any Loan Document or any Lien granted under a Loan Document shall (except in accordance with its terms or due to the action or inaction of any Secured Party that is solely within such Secured Party's control), in whole or in part, terminate, cease to be effective or cease to be the legally valid, binding and enforceable obligation of Holdings, the Borrower or any Subsidiary subject thereto; Holdings, the Borrower, any Subsidiary or any other party shall, directly or indirectly, contest in any manner such effectiveness, validity, binding nature or enforceability; or, except as permitted under any Loan Document or due to the action or inaction of any Secured Party that is solely within such Secured Party's control, any Lien securing any Obligation shall, in whole or in part, cease to be a perfected first priority Lien.
- (j) <u>Key Permit Events</u>. Except as would not reasonably be expected to have a Material Adverse Effect, any Key Permit or any of Holdings', the Borrower's or any Subsidiary's material rights or interests thereunder is terminated or amended in any manner adverse to Holdings, the Borrower or any Subsidiary in any material respect.
- (k) <u>Material Adverse Change</u>. Any circumstance occurs that has had or would reasonably be expected to have a Material Adverse Effect.
- (l) <u>License Agreement</u>. A CoC Transaction (as defined in the License Agreement on the date hereof) or an event of the type described in the last paragraph of Section 20.09 of the License Agreement (as in existence on the date hereof and subject to any exceptions contained therein but without regard to whether Bioprojet has provided its consent to such CoC Transaction or event (to the extent such consent is required under the terms thereof), unless such consent shall have been obtained without the payment of any consideration in excess of \$1,000,000 with respect thereto) shall occur, unless the Administrative Agent has provided its prior written consent to such CoC Transaction or event.
- (m) <u>Regulatory Matters</u>. If any of the following occurs: (i) the FDA, CMS, EMA or any other Governmental Authority (A) delivers a letter or other written communication to Holdings, the Borrower or its Subsidiaries asserting that any Product lacks a required Regulatory Authorization, which assertion is not withdrawn or otherwise resolved within 45 days after such Person's receipt of such letter or other written communication or (B) initiates enforcement action against or issues a warning letter with respect to Holdings, the Borrower or any of the Subsidiaries, or any of their Products or the manufacturing facilities therefor, that causes Holdings, the

Borrower or such Subsidiary to discontinue or suspend the sale of, or withdraw, any of its Products or causes a delay in the offering of any of its Products, which discontinuance, withdrawal or delay would reasonably be expected to last for more than 45 days; (ii) a recall that would reasonably be expected to result in a Material Adverse Effect; or (iii) Holdings, the Borrower or any of the Subsidiaries enters into a settlement agreement with the FDA, CMS, EMA or any other Governmental Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions in excess of \$2,000,000.

(n) Key Contracts. (i) Any material default or material breach by Holdings, the Borrower or any of the Subsidiaries occurs and is continuing under any of the Key Contracts, which material default or material breach is not cured or waived within any express grace period therein provided and would permit any Person (other than Holdings, the Borrower or any Subsidiary) party to any Designated Key Contract to have any termination right thereunder; provided that any Default or Event of Default under this Section 9.1(n)(i) caused by such material breach shall be automatically waived and cured under this Agreement and the other Loan Documents without any action on the part of any Secured Party immediately following the waiver and/or cure of the breach or default under the applicable Designated Key Contract or (ii) any of the Designated Key Contracts is terminated for any reason, other than (A) as a result of any expiration of such Designated Key Contract in accordance with its own terms or (B) with respect to the Designated Key Contracts described in clauses (c) – (h) in the definition of "Key Contracts," in connection with the replacement or termination of such Designated Key Contracts by the Borrower or the applicable Subsidiary in accordance with its reasonable business judgment and so long as the replacement or termination thereof does not result in a material and adverse diminution or deterioration of the business of the Borrower and its Subsidiaries (taken as a whole) relative to the business as was in effect immediately prior to such replacement or termination.

SECTION 9.2 <u>Action if Bankruptcy</u>. If any Event of Default described in clauses (i) through (iv) of <u>Section 9.1(h)</u> with respect to the Borrower shall occur, the Commitments (if not theretofore terminated) shall automatically terminate and the outstanding principal amount of the Loans and all other Obligations shall automatically be and become immediately due and payable, without notice or demand to any Person.

SECTION 9.3 Action if Other Event of Default. If any Event of Default (other than any Event of Default described in clauses (i) through (iv) of Section 9.1(h)) shall occur for any reason, whether voluntary or involuntary, and be continuing, the Administrative Agent may, and shall at the direction of the Required Lenders, by notice to the Borrower declare all or any portion of the outstanding principal amount of the Loans and other Obligations to be due and payable and the Commitments (if not theretofore terminated) to be terminated, whereupon the full unpaid amount of the Loans and other Obligations which shall be so declared due and payable shall be and become immediately due and payable, without further notice, demand or presentment, and the Commitments shall terminate; provided that, in the case of an Event of Default

under <u>Section 9.1(k)</u>, Administrative Agent shall provide five (5) Business Days' prior written notice to the Borrower before exercising any right or remedy, whereby during such five (5) Business Day period, Administrative Agent shall make itself available to discuss in good faith any proposed solution to such circumstance and the Borrower may take any action otherwise permitted under the Loan Documents (x) as required so that such circumstances no longer exist (to the extent curable), (y) to show evidence that no such circumstance has occurred or (z) to provide a plan detailing how the Borrower will mitigate the effect of such circumstance, which, in each case, at such time as such evidence or plans are provided to Administrative Agent, Administrative Agent shall promptly re-determine in good faith whether an Event of Default still exists with respect to <u>Section 9.1(k)</u> and if, as a result of such re-determination, no Event of Default under <u>Section 9.1(k)</u> remains existing, any proposed or expected Event of Default under <u>Section 9.1(k)</u> will immediately be deemed to be waived and cured, without any further action by any Person

SECTION 9.4 <u>Application of Funds</u>. After the exercise of remedies provided for in <u>Section 9.3</u> (or after the Loans have automatically become immediately due and payable as set forth in <u>Section 9.2</u>), any amounts received by any Lender or the Administrative Agent on account of the Obligations shall be applied in the following order:

<u>First</u>, to payment of that portion of the Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Administrative Agent and amounts payable under <u>Article</u> III) payable to the Administrative Agent in its capacity as such;

<u>Second</u>, to payment of that portion of the Obligations constituting fees, indemnities and other amounts (other than principal and interest) payable to the Lenders (including fees, charges and disbursements of counsel to the respective Lenders) arising under the Loan Documents and amounts payable under <u>Section 4.3</u>, ratably among them in proportion to the respective amounts described in this <u>clause Second</u> payable to them;

<u>Third</u>, to payment of that portion of the Obligations constituting accrued and unpaid interest on the Loans and amounts payable under <u>Sections 3.7</u>, <u>3.8</u> and <u>3.11</u>, ratably among the Lenders in proportion to the respective amounts described in this <u>clause Third</u> held by them;

<u>Fourth</u>, to payment of that portion of the Obligations constituting accrued and unpaid principal of the Loans, ratably among the Lenders in proportion to the respective amounts described in this <u>clause Fourth</u> held by them; and

<u>Last</u>, the balance, if any, after all of the Obligations have been indefeasibly paid in full, to the Borrower or as otherwise required by law.

ARTICLE X MISCELLANEOUS PROVISIONS

SECTION 10.1 <u>Waivers, Amendments, Etc.</u> No amendment or waiver of any provision of this Agreement or any other Loan Document, and no consent to any departure by the Borrower or any Guarantor therefrom, shall be effective unless in writing signed by the Required Lenders and the Borrower or the applicable Guarantor, as the case may be, and acknowledged by the Administrative Agent, and each such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; <u>provided</u>, further, that

- (a) no such amendment, waiver or consent shall:
- (i) extend or increase the Commitment of a Lender (or reinstate any Commitment terminated pursuant to <u>Section 9.2</u>) without the written consent of such Lender whose Commitment is being extended or increased (it being understood and agreed that a waiver of any condition precedent set forth in <u>Article V</u> or a waiver of any Default or a mandatory reduction in Commitments is not considered an extension or increase in Commitments of any Lender);
- (ii) postpone any date fixed by this Agreement or any other Loan Document for any payment of principal (excluding mandatory prepayments), interest, Repayment Premiums, fees or other amounts due to the Lenders (or any of them) without the written consent of each Lender entitled to receive such payment (it being understood that a waiver of any Default or Event of Default shall not constitute such a postponement);
- (iii) reduce the principal of, the rate of interest specified herein on or any Repayment Premium specified herein on any Loan, or any fees or other amounts payable hereunder or under any other Loan Document without the written consent of each Lender entitled to receive such payment of principal, interest, fees or other amounts (other than any such reduction in connection with a waiver of any Default, Event of Default, mandatory prepayment or amendment to any financial covenant);
- (iv) (x) amend or waive any provision of <u>Section 9.4</u>, or (y) amend or waive any provision providing for the pro rata treatment of the Lenders, in each case without the written consent of each Lender directly affected thereby;
- (v) change any provision of this $\underline{\text{Section 10.1(a)}}$ or the definition of "Required Lenders" without the written consent of all the Lenders;
- (vi) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by the Borrower of any of their rights and obligations under this Agreement and the other Loan Documents, or release all or substantially all of the Collateral or release all or substantially all of the Guarantors from their obligations under the Guarantee, in each case without the written consent of all the Lenders;

(vii) (x) amend, waive or modify Section 11.6 hereof, without the consent of the Required Lenders; and

(b) unless also signed by the Administrative Agent, no amendment, waiver or consent shall affect the rights or duties of the Administrative Agent under this Agreement or any other Loan Document;

provided, however, that notwithstanding anything to the contrary herein, (i) each Lender is entitled to vote as such Lender sees fit on any bankruptcy reorganization plan that affects the Loans, and each Lender acknowledges that the provisions of Section 1126(c) of the Bankruptcy Code of the United States supersedes the unanimous consent provisions set forth herein and (ii) the Required Lenders shall determine whether or not to allow the Borrower or any Guarantor to use cash collateral in the context of a bankruptcy or insolvency proceeding and such determination shall be binding on all of the Lenders.

Any payments, fees or other consideration (other than reimbursements for out-of-pocket expenses) received by or on behalf of the Administrative Agent or any of the Lenders in respect of any amendment, waiver or consent under the Loan Documents shall be distributed to the Lenders on a pro rata basis.

SECTION 10.2 Notices; Time.

- (a) All notices and other communications provided under any Loan Document shall be in writing or by facsimile and addressed, delivered or transmitted, if to the Borrower or the Lenders, to the applicable Person at its address or facsimile number set forth on Schedule 10.2 hereto, or at such other address or facsimile number as may be designated by such party in a notice to the other parties. Any notice, if mailed and properly addressed with postage prepaid or if properly addressed and sent by pre-paid courier service, shall be deemed given when received; any notice, if transmitted by facsimile, shall be deemed given when the confirmation of transmission thereof is received by the transmitter. Unless otherwise indicated, all references to the time of a day in a Loan Document shall refer to New York City time.
- (b) The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic loan notices) purportedly given by or on behalf of the Borrower or any Guarantor even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Borrower and each Guarantor shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of the Borrower and each Guarantor; provided that such indemnity shall not, as to any Person be available to the extent that such losses, costs, expenses or liabilities are determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from the gross negligence or willful misconduct of such

Person. All telephonic notices to and other telephonic communications with the Administrative Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.

SECTION 10.3 [Reserved].

SECTION 10.4 Indemnification; Expenses; and Damage Waiver.

- (a) In consideration of the execution and delivery of this Agreement by the Lenders and the Administrative Agent, the Borrower hereby indemnifies, agrees to defend, exonerates and holds each Lender and the Administrative Agent (and any sub-agent thereof) and each Related Party of any of the foregoing Persons (collectively, the "Indemnified Parties") free and harmless from and against any and all actions, causes of action, suits, losses, costs, liabilities, obligations and damages, claims and expenses incurred in connection therewith (irrespective of whether any such Indemnified Party is a party to the action for which indemnification hereunder is sought), including reasonable and documented out-of-pocket attorneys' (but limited, in the case of such fees and expenses, to the reasonable and documented out-of-pocket fees and expenses of one counsel to all Indemnified Parties taken as a whole in each applicable jurisdiction, one special counsel if necessary and, in the case of an actual or potential conflict of interest, one additional counsel in each relevant jurisdiction to each group of similarly situated affected Indemnified Parties) and professionals' fees and disbursements (collectively, the "Indemnified Liabilities"), (including, without limitation, Indemnified Liabilities arising out of or relating to (i) the entering into and performance of any Loan Document by any of the Indemnified Parties (including any action brought by or on behalf of the Borrower as the result of any determination by any Lender pursuant to <u>Article V</u> not to fund any Loan), and (ii) any Environmental Liability), except to the extent such Indemnified Liabilities are found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted (x) from any Indemnified Party's gross negligence or willful misconduct or (y) out of or in connection with any Indemnified Liabilities that do not involve an act or omission of Holdings, the Borrowers, the Subsidiaries or their Affiliates and that is brought by an Indemnified Party against another Indemnified Party. If and to the extent that the foregoing indemnification may be unenforceable for any reason, the Borrower agrees to make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable Law.
- (b) <u>Costs and Expenses</u>. Borrower and the Guarantors shall pay (i) all reasonable and documented out-of-pocket expenses incurred by each Lender and the Administrative Agent (including the reasonable and documented out-of-pocket fees, charges and disbursements of counsel for the Administrative Agent and the Lenders and due diligence expenses incurred by the Administrative Agent and the Lenders), in connection with the preparation, negotiation, execution, delivery and administration of this Agreement and the other Investment Documents or any amendments, modifications or waivers of the provisions hereof or thereof (whether or not the transactions contemplated hereby or thereby shall be consummated) and (ii) all reasonable and documented out-of-pocket expenses incurred by the Administrative

Agent or any Lender (including the fees, charges and disbursements of any counsel for the Administrative Agent or any Lender, which shall be limited to the reasonable and documented out-of-pocket fees and expenses of one counsel to all the Administrative Agent and the Lenders taken as a whole in each applicable jurisdiction, one special counsel if necessary and, in the case of an actual or potential conflict of interest, one additional counsel in each relevant jurisdiction to each group of similarly situated affected Administrative Agent or the Lenders), in connection with the enforcement or protection of its rights (A) in connection with this Agreement and the other Investment Documents, including its rights under this Section 10.4, or (B) in connection with the Loans made hereunder, including all such out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Loans.

- (c) Reimbursement by Lenders. To the extent that the Borrower and the Guarantors for any reason fail to indefeasibly pay any amount required under <u>subsection (a)</u> or <u>(b)</u> of this <u>Section 10.4</u> to be paid by them to the Administrative Agent (or any sub-agent thereof) or any Related Party thereof, each Lender severally agrees to pay to the Administrative Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's pro rata share (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought based on each Lender's share of the Total Credit Exposure at such time) of such unpaid amount (including any such unpaid amount in respect of a claim asserted by such Lender), such payment to be made severally among them based on such Lenders' Applicable Percentages (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought); <u>provided</u>, further, that the unreimbursed expense or indemnified loss, claim, damage, liability or related expense, as the case may be, was incurred by or asserted against the Administrative Agent (or any such sub-agent) in connection with such capacity.
- (d) <u>Waiver of Consequential Damages</u>, <u>Etc.</u> To the fullest extent permitted by applicable law, none of the Borrower, any Guarantor or any Indemnified Party shall assert, and such Persons hereby waives, and acknowledges that no other Person shall have, any claim against any the Borrower, any Guarantor or any Indemnified Party, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) arising out of, in connection with, or as a result of, this Agreement, any other Investment Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Loan or the use of the proceeds thereof. None of the Borrower, any Guarantor or any Indemnified Party shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Investment Documents or the transactions contemplated hereby or thereby.
 - (e) Payments. All amounts due under this Section 10.4 shall be payable not later than ten Business Days after demand therefor.

SECTION 10.5 <u>Survival</u>. The obligations of the Borrower under <u>Section 4.1</u>, <u>Section 4.2</u>, <u>Section 4.3</u> and <u>Section 10.4</u>, shall in each case survive any assignment by any Lender and the occurrence of the Termination Date. The representations and warranties made by the Borrower in each Loan Document shall survive the execution and delivery of such Loan Document. The agreements in this <u>Section 10.5</u> and the indemnity provisions of <u>Section 10.4(c)</u> shall survive the resignation of the Administrative Agent, the replacement of any Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all the other Obligations. All representations and warranties made hereunder and in any other Loan Document or other document delivered pursuant hereto or thereto or in connection herewith or therewith shall survive the execution and delivery hereof and thereof. Such representations and warranties have been or will be relied upon by the Administrative Agent and each Lender, regardless of any investigation made by the Administrative Agent or any Lender or on their behalf and notwithstanding that the Administrative Agent or any Lender may have had notice or knowledge of any Default at the time of any Borrowing, and shall continue in full force and effect as long as any Loan or any other Obligation hereunder shall remain unpaid or unsatisfied.

SECTION 10.6 <u>Severability</u>. Any provision of any Loan Document which is prohibited or unenforceable in any jurisdiction shall, as to such provision and such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of such Loan Document affecting the validity or enforceability of such provision in any other jurisdiction.

SECTION 10.7 <u>Headings</u>. The various headings of each Loan Document are inserted for convenience only and shall not affect the meaning or interpretation of such Loan Document or any provisions thereof.

SECTION 10.8 Execution in Counterparts, Effectiveness, Etc. This Agreement may be executed by the parties hereto in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. This Agreement shall become effective when counterparts hereof executed on behalf of the Borrower and the Lenders, shall have been received by the Lenders. Delivery of an executed counterpart of a signature page to this Agreement by email (e.g., "pdf" or "tiff") or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

SECTION 10.9 Governing Law; Entire Agreement. EACH LOAN DOCUMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT CONTEMPLATED HEREBY AND THEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). The Loan Documents constitute the entire understanding among the parties hereto with respect to the subject matter thereof and supersede any prior agreements, written or oral, with respect thereto.

SECTION 10.10 Successors and Assigns.

- (a) <u>Successors and Assigns Generally</u>. The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the Parties hereto and thereto and their respective successors and assigns permitted hereby, except that the Borrower may not assign or otherwise transfer any of its rights or obligations hereunder or thereunder without the prior written consent of the Administrative Agent and each Lender and no Lender may assign or otherwise transfer any of its rights or obligations hereunder except (i) to an assignee in accordance with the provisions of <u>subsection (b)</u> of this Section or (ii) by way of pledge or assignment of a security interest subject to the restrictions of <u>subsection (d)</u> of this Section (and any other attempted assignment or transfer by any party hereto shall be null and void). Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby and, to the extent expressly contemplated hereby, the Related Parties of each of the Administrative Agent and the Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement. No assignment or transfer of any Commitment or Loan shall be effective until receipt and acceptance into the Register by the Administrative Agent of a fully executed Assignment and Assumption effecting the assignment or transfer thereof, together with the required forms and certificates regarding tax matters and any fees payable in connection with such assignment, in each case, as provided in <u>subsection (b)</u>. The date of such assignment shall be referred to herein as the "Assignment Effective Date."
- (b) <u>Assignments by Lenders</u>. Any Lender may at any time assign to one or more assignees all or a portion of its rights and obligations under this Agreement and the other Loan Documents (including all or a portion of its Commitment and the Loans at the time owing to it); provided that any such assignment shall be subject to the following conditions:

(i) Minimum Amounts.

A. in the case of an assignment of the entire remaining amount of the assigning Lender's Commitment and/or the Loans at the time owing to it or contemporaneous assignments to related Approved Funds that equal at least the amount specified in paragraph(b)(i)(B) of this Section in the aggregate or in the case of an assignment to a Lender, an Affiliate of a Lender or an Approved Fund, no minimum amount need be assigned; and

B. in any case not described in $\underline{\text{subsection}}(\underline{b})(\underline{i})(\underline{A})$ of this $\underline{\text{Section}}$, the aggregate amount of the Commitment (which for this purpose includes Loans outstanding thereunder) or, if the

applicable Commitment is not then in effect, the principal outstanding balance of the Loans of the assigning Lender subject to each such assignment, determined as of the date the Assignment and Assumption with respect to such assignment is delivered to the Administrative Agent or, if "Trade Date" is specified in the Assignment and Assumption, as of the Trade Date, shall not be less than \$1,000,000 unless each of the Administrative Agent and, so long as no Event of Default has occurred and is continuing, the Borrower otherwise consents (each such consent not to be unreasonably withheld or delayed);

- (ii) <u>Proportionate Amounts</u>. Each partial assignment shall be made as an assignment of a proportionate part of all of the assigning Lender's rights and obligations under this Agreement with respect to the Loans or the Commitment assigned;
- (iii) <u>Required Consents</u>. No consent shall be required for any assignment except to the extent required by <u>subsection (b)(i)(B)</u> of this <u>Section</u> and, in addition, the consent of the Administrative Agent, the Required Lenders and, so long as no Event of Default has occurred and is continuing, the Borrower (in each case, such consent not to be unreasonably withheld or delayed) shall be required for assignments to a Person that is not a Lender, an Affiliate of a Lender or an Approved Fund.
- (iv) <u>Assignment and Assumption</u>. Assignments and assumptions of Loans and Commitments by Lenders shall be effected by manual execution and delivery to the Administrative Agent of an Assignment and Assumption. Assignments made pursuant to the foregoing provision shall be effective as of the Assignment Effective Date, subject to acceptance and recording thereof in the Register by the Administrative Agent pursuant to <u>Section 10.10(c)</u>. In connection with all assignments there shall be delivered to the Administrative Agent such forms, certificates or other evidence, if any, with respect to Taxes as the assignee under such Assignment and Assumption may be required to deliver pursuant to <u>Section 4.3</u>, together with payment to the Administrative Agent of a registration and processing fee of \$3,500, which may be waived or reduced at the sole discretion of the Administrative Agent.
- (v) <u>No Assignment to Certain Persons</u>. No such assignment shall be made to any Disqualified Institution (except if an Event of Default has occurred or is continuing at the time of such assignment), the Borrower or any Guarantor or any Affiliate or Subsidiary of the Borrower or any Guarantor, or any Person who, upon becoming a Lender hereunder, would constitute any of the foregoing Persons (other than to the Lenders on the date hereof and their respective Affiliates). Any assignment or transfer by a Lender of rights or obligations under this Agreement that does not comply with this Section 10.10(b) shall be absolutely void ab initio.

- (vi) Subject to acceptance and recording thereof by the Administrative Agent pursuant to <u>subsection</u> (c) of this <u>Section</u>, from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of a Lender under this Agreement, and the assigning Lender thereunder shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of the assigning Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) but shall continue to be entitled to the benefits of <u>Sections 4.3</u> and <u>10.4</u> with respect to facts and circumstances occurring prior to the effective date of such assignment. Upon request, the Borrower (at its expense) shall execute and deliver a Note to the assignee Lender.
- (c) <u>Register</u>. The Administrative Agent, acting solely for this purpose as an agent of the Borrower (and such agency being solely for tax purposes), shall maintain at the Administrative Agent's Office a copy of each Assignment and Assumption delivered to it (or the equivalent thereof in electronic form) and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "<u>Register</u>"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.
- (d) <u>Certain Pledges</u>. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement (including under its Note, if any) to secure obligations of such Lender, including any pledge or assignment to secure obligations to a Federal Reserve Bank; <u>provided</u> that no such pledge or assignment shall (i) release such Lender from any of its obligations hereunder or substitute any such pledgee or assignee for such Lender as a party hereto or (ii) be to any Disqualified Institution (except if an Event of Default has occurred or is continuing at the time of such) and any prohibited pledge or assignment shall be absolutely void ab initio.

SECTION 10.11 Other Transactions. Nothing contained herein shall preclude any Lender or any of its Affiliates from engaging in any transaction, in addition to those contemplated by the Investment Documents, with the Borrower or any of its Affiliates in which the Borrower or such Affiliate is not restricted hereby from engaging with any other Person.

SECTION 10.12 Forum Selection and Consent to Jurisdiction. ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN

CONNECTION WITH, ANY LOAN DOCUMENT, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE ADMINISTRATIVE AGENT, ANY LENDER OR THE BORROWER IN CONNECTION HEREWITH OR THEREWITH SHALL BE BROUGHT AND MAINTAINED IN THE COURTS OF THE BOROUGH OF MANHATTAN IN THE CITY OF NEW YORK IN THE STATE OF NEW YORK OR IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK; PROVIDED THAT ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT THE ADMINISTRATIVE AGENT'S OR THE LENDERS' OPTION, IN THE COURTS OF ANY JURISDICTION WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND. EACH PARTY HERETO IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF NEW YORK AT THE ADDRESS FOR NOTICES SPECIFIED IN SECTION 10.2. EACH PARTY HERETO HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY HAVE OR HEREAFTER MAY HAVE TO THE LAYING OF VENUE OF ANY SUCH LITIGATION BROUGHT IN ANY SUCH COURT REFERRED TO ABOVE AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM. TO THE EXTENT THAT ANY PARTY HERETO HAS OR HEREAFTER MAY ACQUIRE ANY IMMUNITY FROM JURISDICTION OF ANY COURT OR FROM ANY LEGAL PROCESS (WHETHER THROUGH SERVICE OR NOTICE, ATTACHMENT PRIOR TO JUDGMENT, ATTACHMENT IN AID OF EXECUTION OR OTHERWISE) WITH RESPECT TO ITSELF OR ITS PROPERTY, SUCH PARTY HEREBY IRREVOCABLY WAIVES TO THE FULLEST EXTENT PERMITTED BY LAW SUCH IMMUNITY IN RESPECT OF ITS OBLIGATIONS UNDER THE LOAN DOCUMENTS.

SECTION 10.13 <u>Waiver of Jury Trial</u>. THE ADMINISTRATIVE AGENT, THE LENDERS AND THE BORROWER HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVE TO THE FULLEST EXTENT PERMITTED BY LAW ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, EACH LOAN DOCUMENT, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE ADMINISTRATIVE AGENT, ANY LENDER OR THE BORROWER IN CONNECTION THEREWITH. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT IT HAS RECEIVED FULL AND SUFFICIENT CONSIDERATION FOR THIS PROVISION (AND EACH OTHER PROVISION OF EACH OTHER LOAN DOCUMENT TO WHICH IT IS A PARTY) AND THAT THIS PROVISION IS A MATERIAL INDUCEMENT FOR THE OTHER PARTIES HERETO ENTERING INTO THE LOAN DOCUMENTS.

SECTION 10.14 Confidential Information. Subject to the provisions of Section 10.15, at all times prior to the Termination Date, the Receiving Party shall keep confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party's employees, advisors or consultants who have a need to know such information to assist such Party in the performance of such Party's obligations or in the exercise of such Party's rights hereunder and who are subject to reasonable obligations of confidentiality consistent with this Section 10.14 (collectively, "Recipients"). Notwithstanding anything to the contrary set forth herein, (a) any Lender may disclose this Agreement and the terms and conditions hereof and any information related hereto, to (i) its Affiliates, (ii) potential and actual assignees of any of such Lender's rights hereunder and (iii) potential and actual investors in, or lenders to, such Lender (including, in each of the foregoing cases, such Person's employees, advisors or consultants); provided that in each case, unless an Event of Default has occurred and is continuing, each such Recipient shall be subject to reasonable obligations of confidentiality; and (b) upon receiving consent from the Lenders, which consent shall not be unreasonably withheld, delayed or conditioned, the Borrower may disclose this Agreement and the terms and conditions hereof and information related hereto, to potential or actual permitted acquirers or assignees, collaborators and other (sub)licensees, permitted subcontractors, investment bankers, investors, lenders (including, in each of the foregoing cases, such Person's employees, advisors or consultants who have a need to receive and review such information); provided that in each case, each such Recipient shall be subject to reasonable obligations of confidentiality. In addition to the foregoing, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in order to comply with applicable Laws (including any securities law or regulation or the rules of a securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance, provided that the Receiving Party (x) will only disclose those portions of the Confidential Information that are necessary or required to be so disclosed, and (y) to the extent legally permissible, will notify the Disclosing Party of the Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow the Disclosing Party time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed.

SECTION 10.15 <u>Exceptions to Confidentiality</u>. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:

- (a) that is or hereafter becomes part of the public domain (other than as a result of a disclosure by the Receiving Party or its Recipients in violation of this Agreement);
- (b) that is received from a Third Party without restriction on disclosure and without, to the knowledge of the Receiving Party, breach of any agreement between such Third Party and the Disclosing Party;

- (c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on disclosure prior to its receipt from the Disclosing Party;
 - (d) that is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or
- (e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party without use of or reference to the Confidential Information.

SECTION 10.16 No Waiver; Cumulative Remedies; Enforcement. No failure by any Lender or the Administrative Agent to exercise, and no delay by any such Person in exercising, any right, remedy, power or privilege hereunder or under any other Loan Document shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided, and provided under each other Loan Document, are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

Notwithstanding anything to the contrary contained herein or in any other Loan Document, the authority to enforce rights and remedies hereunder and under the other Loan Documents against the Borrower and the Guarantors or any of them shall be vested exclusively in, and all actions and proceedings at law in connection with such enforcement shall be instituted and maintained exclusively by, the Administrative Agent in accordance with Section 11.1 for the benefit of all the Lenders; provided, however, that the foregoing shall not prohibit (a) the Administrative Agent from exercising on its own behalf the rights and remedies that inure to its benefit (solely in its capacity as Administrative Agent) hereunder and under the other Loan Documents, (b) any Lender from exercising setoff rights in accordance with Section 4.5 (subject to the terms of Section 4.4(e)), or (c) any Lender from filing proofs of claim or appearing and filing pleadings on its own behalf during the pendency of a proceeding relative to the Borrower or any Guarantor under any Debtor Relief Law or any proceedings arising out of or in connection with an Insolvency Event; and provided, further, that if at any time there is no Person acting as Administrative Agent hereunder and under the other Loan Documents, then (i) the Required Lenders shall have the rights otherwise ascribed to the Administrative Agent pursuant to Section 11.1 and (ii) in addition to the matters set forth in clauses (b) and (c) of the preceding proviso and subject to Section 4.4(e), any Lender may, with the consent of the Required Lenders, enforce any rights and remedies available to it and as authorized by the Required Lenders.

SECTION 10.17 <u>Payments Set Aside</u>. To the extent that any payment by or on behalf of the Borrower or any Guarantor is made to the Administrative Agent or any Lender, or the Administrative Agent or any Lender exercises its right of setoff, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by the Administrative Agent or such Lender in its discretion) to be repaid to a trustee, receiver, receiver, manager, monitor or any other party, in connection with any proceeding under any Debtor Relief Law, any proceedings arising out of or in connection with an Insolvency Event or otherwise,

then (a) to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred, and (b) each Lender severally agrees to pay to the Administrative Agent upon demand its applicable share (without duplication) of any amount so recovered from or repaid by the Administrative Agent, <u>plus</u> interest thereon from the date of such demand to the date such payment is made at a rate per annum equal to the Federal Funds Rate from time to time in effect. The obligations of the Lenders under clause (b) of the preceding sentence shall survive the payment in full of the Obligations and the termination of this Agreement.

SECTION 10.18 Electronic Execution of Assignments and Certain Other Documents. The words "execute," "execution," "signed," "signature" and words of like import in any Assignment and Assumption or in any amendment or other modification hereof (including waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

ARTICLE XI ADMINISTRATIVE AGENT

SECTION 11.1 Appointment and Authority.

- (a) Each of the Lenders hereby irrevocably appoints OrbiMed Royalty & Credit Opportunities III, LP to act on its behalf as the Administrative Agent hereunder and under the other Loan Documents and authorizes the Administrative Agent to take such actions on its behalf and to exercise such powers as are delegated to the Administrative Agent by the terms hereof or thereof, together with such actions and powers as are incidental thereto. The provisions of this Article are solely for the benefit of the Administrative Agent and the Lenders, and neither the Borrower nor any Guarantor shall have rights as a third party beneficiary of any of such provisions. It is understood and agreed that the use of the term "agent" herein or in any other Loan Documents (or any other similar term) with reference to the Administrative Agent is not intended to connote any fiduciary or other implied (or express) obligations arising under agency doctrine of any applicable law. Instead such term is used as a matter of market custom, and is intended to create or reflect only an administrative relationship between contracting parties.
- (b) The Administrative Agent shall also act as the "collateral agent" under the Loan Documents, and each of the Lenders hereby irrevocably appoints and authorizes the Administrative Agent to act as the agent of such Lender for purposes of acquiring, holding and enforcing any and all Liens on Collateral granted by any of the Borrower and the Guarantors to secure any of the Obligations, together with such powers and discretion as are incidental thereto. In this connection, the Administrative Agent, as "collateral agent"

(and any co-agents, sub-agents and attorneys-in-fact appointed by the Administrative Agent pursuant to <u>Section 11.5</u> for purposes of holding or enforcing any Lien on the Collateral (or any portion thereof) granted under the Security Agreement, or for exercising any rights and remedies thereunder at the direction of the Administrative Agent), shall be entitled to the benefits of all provisions of <u>Article X</u> (including <u>Section 10.4(c)</u>), as though such co-agents, sub-agents and attorneys-in-fact were the "collateral agent" under the Loan Documents) and this <u>Article XI</u> as if set forth in full herein with respect thereto.

SECTION 11.2 <u>Rights as a Lender</u>. The Person serving as the Administrative Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Administrative Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Administrative Agent hereunder in its individual capacity. Such Person and its Affiliates may accept deposits from, lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with the Borrower, any Guarantor or any Affiliate thereof as if such Person were not the Administrative Agent hereunder and without any duty to account therefor to the Lenders.

SECTION 11.3 Exculpatory Provisions. The Administrative Agent shall not have any duties or obligations except those expressly set forth herein and in the other Loan Documents, and its duties hereunder shall be administrative in nature. Without limiting the generality of the foregoing, the Administrative Agent:

- (a) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;
- (b) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Administrative Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in the other Loan Documents), provided that the Administrative Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Administrative Agent to liability or that is contrary to any Loan Document or applicable law, including for the avoidance of doubt any action that may be in violation of the automatic stay under any Debtor Relief Law; and
- (c) shall not, except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to Holdings, any Borrower and any of the Subsidiaries that is communicated to or obtained by the Person serving as the Administrative Agent or any of its Affiliates in any capacity.

The Administrative Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment. The Administrative Agent shall be deemed not to have knowledge of any Default or Event of Default unless and until notice describing such Default or Event of Default is given in writing to the Administrative Agent by the Borrower, or a Lender.

The Administrative Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Article V or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Administrative Agent.

SECTION 11.4 Reliance by Administrative Agent.

- (a) The Administrative Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, Internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Administrative Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. In determining compliance with any condition hereunder to the making of a Loan, that by its terms must be fulfilled to the satisfaction of a Lender, the Administrative Agent may presume that such condition is satisfactory to such Lender unless the Administrative Agent shall have received notice to the contrary from such Lender prior to the making of such Loan. The Administrative Agent may consult with legal counsel (who may be counsel for Holdings, the Borrower or its Subsidiaries), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.
- (b) Reliance by Administrative Agent and Lenders. The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic loan notices) purportedly given by or on behalf of the Borrower or any of the Guarantors even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Borrower and the Guarantors shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of the Borrower or any Guarantor; provided that such indemnity shall not, as to any Person be available to the extent that such losses, costs, expenses or liabilities are determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from the gross negligence or willful misconduct of such Person or its Related Parties. All telephonic notices to and other telephonic communications with the Administrative Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.

SECTION 11.5 Delegation of Duties. The Administrative Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Administrative Agent. The Administrative Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The rights, benefits and privileges (including the exculpatory and indemnification provisions) of Article X and this Article XI shall apply to any such sub-agent and to the Related Parties of the Administrative Agent and any such sub-agent, and shall apply to their respective activities in connection with the syndication of the credit facilities provided for herein as well as activities as Administrative Agent. The Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that the Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agents. Notwithstanding anything herein to the contrary, with respect to each sub-agent appointed by the Administrative Agent, (i) such sub-agent shall be a third party beneficiary under this Agreement with respect to all such rights, benefits and privileges (including exculpatory rights and rights to indemnification) and shall have all of the rights and benefits of a third party beneficiary, including an independent right of action to enforce such rights, benefits and privileges (including exculpatory rights and rights to indemnification) directly, without the consent or joinder of any other Person, against any or all of the Borrower, the Guarantors and the Lenders, (ii) any modification to such rights, benefits and privileges (including exculpatory rights and rights to indemnification) shall not be effective as against such sub-agent without its written consent thereto, and (iii) such sub-agent shall only have obligations to the Administrative Agent and not to the Borrower or any Guarantor, Lender or any other Person and none of the Borrower, the Guarantors, the Lenders or any other Person shall have any rights, directly or indirectly, as a third party beneficiary or otherwise, against such subagent.

SECTION 11.6 Resignation or Removal of Administrative Agent. The Administrative Agent may resign as Administrative Agent at any time by giving thirty (30) days advance notice thereof to the Lenders and the Borrower and, thereafter, the retiring Administrative Agent shall be discharged from its duties and obligations hereunder. Upon any such resignation, the Required Lenders shall have the right to appoint a successor Administrative Agent. No less than thirty (30) days' following the delivery of such written notice, the Required Lenders shall have the right, in consultation with the Borrower, to appoint a successor, which shall be a bank with an office in the United States, or an Affiliate of any such bank with an office in the United States, with whom the Lenders shall be dealing on an arm's length basis. Upon the acceptance of any appointment as Administrative Agent hereunder by a successor Administrative Agent, such successor Administrative Agent shall thereupon succeed to and become vested with all rights, powers, privileges and duties of the retiring Administrative Agent. After any retiring Administrative Agent's resignation hereunder as Administrative Agent or upon a removal of the Administrative Agent, the provisions of this Section 11.6 shall continue in effect for its benefit in respect of any actions taken or omitted to be taken by it while it was acting as Administrative Agent. If no successor has accepted appointment as Administrative Agent by the date which is thirty (30) days following a retiring Administrative Agent's notice of resignation or removal, the

retiring Administrative Agent's resignation or removal shall nevertheless thereupon become effective and the Required Lenders shall perform all of the duties of the Administrative Agent hereunder until such time, if any, as the Required Lenders appoint a successor agent as provided for above.

SECTION 11.7 Non-Reliance on Administrative Agent and Other Lenders. Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement. Each Lender also acknowledges that it will, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

SECTION 11.8 <u>Administrative Agent May File Proofs of Claim.</u> In case of the pendency of any receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition or other judicial proceeding relative to the Borrower or any Guarantor, the Administrative Agent (irrespective of whether the principal of any Loan shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Administrative Agent shall have made any demand on the Borrower) shall be entitled and empowered, by intervention in such proceeding or otherwise:

- (a) to file and prove a claim for the whole amount of the principal and interest owing and unpaid in respect of the Loans and all other Obligations that are owing and unpaid and to file such other documents as may be necessary or advisable in order to have the claims of the Lenders and the Administrative Agent (including any claim for the reasonable compensation, expenses, disbursements and advances of the Lenders and the Administrative Agent and their respective agents and counsel and all other amounts due the Lenders and the Administrative Agent under Section 10.4) allowed in such judicial proceeding; and
 - (b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, receiver-manager, monitor, assignee, trustee, liquidator, sequestrator or other similar official in any such judicial proceeding is hereby authorized by each Lender to make such payments to the Administrative Agent and, in the event that the Administrative Agent shall consent to the making of such payments directly to the Lenders, to pay to the Administrative Agent any amount due for the reasonable compensation, expenses, disbursements and advances of the Administrative Agent and its agents and counsel, and any other amounts due the Administrative Agent under Section 10.4.

Nothing contained herein shall be deemed to authorize the Administrative Agent to authorize or consent to or accept or adopt on behalf of any Lender any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Lender or to authorize the Administrative Agent to vote in respect of the claim of any Lender in any such proceeding.

SECTION 11.9 Collateral and Guarantee Matters. The Lenders irrevocably authorize the Administrative Agent, at its option and in its discretion,

- (a) to release any Lien on any Collateral granted to or held by the Administrative Agent under any Loan Document (i) upon payment in full of all Obligations, (ii) that is sold or otherwise disposed of to a Person that is not the Borrower or any Guarantor as part of or in connection with any sale or other Disposition permitted hereunder and under the other Loan Document or any Casualty Event, or (iii) as approved in accordance with Section 10.1; and
- (b) to release any Guarantor from its obligations under the Guarantee if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Loan Documents.

Upon request by the Administrative Agent at any time, the Required Lenders will confirm in writing the Administrative Agent's authority to release its interest in particular types or items of property, or to release any Guarantor from its obligations under the Guarantee, pursuant to this Section 11.9.

The Administrative Agent shall not be responsible for or have a duty to ascertain or inquire into any representation or warranty regarding the existence, value or collectability of the Collateral, the existence, priority or perfection of the Administrative Agent's Lien thereon, or any certificate prepared by the Borrower or any Guarantor in connection therewith, nor shall the Administrative Agent be responsible or liable to the Lenders for any failure to monitor or maintain any portion of the Collateral.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

HARMONY BIOSCIENCES, LLC, as the Borrower

By: /s/ John Jacobs

Name: John Jacobs

Title: Chief Executive Officer

[Signature Page to Credit Agreement]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

ORBIMED ROYALTY & CREDIT OPPORTUNITIES III,

LP,

as the Administrative Agent and as a Lender

By: OrbiMed ROF III LLC, its General Partner

By: OrbiMed Advisors LLC, its Managing Member

By: /s/ W. Carter Neild

Name: W. Carter Neild Title: Member

ORBIMED ROYALTY OPPORTUNITIES II, LP, $\,$

as a Lender

By: OrbiMed ROF II LLC, its General Partner

By: OrbiMed Advisors LLC, its Managing Member

By: /s/ W. Carter Neild

Name: W. Carter Neild Title: Member

[Signature Page to Credit Agreement]

SCHEDULE 1

[***]

COMMITMENTS AND APPLICABLE PERCENTAGES

	Applicable	
<u>Lender</u>	Percentage	Commitment Amount
OrbiMed Royalty & Credit Opportunities III, LP	75.0%	\$ 150,000,000.00
OrbiMed Royalty Opportunities II, LP	25.0%	\$ 50,000,000.00
Total		\$ 200,000,000.00

SCHEDULE 6.7(a)

LITIGATION

EXISTING SUBSIDIARIES

SCHEDULE 6.15(a)

INTELLECTUAL PROPERTY

(1)

(i) Patents: None

(ii) Trademarks:

<u>Owner</u> Harmony Biosciences, LLC
Harmony Biosciences, LLC
Harmony Biosciences, LLC Harmony Biosciences, LLC
Harmony Biosciences, LLC
Harmony Biosciences, LLC

Domain Names:

abusewakix.com abusewakix.info abusewakix.net

Trademark	Appl. #	Reg. #	Status	Country of Reg.	Appl. Dt	Reg. Dt
REM AT THE WRONG TIME	87954316	N/A	Published (Pending) Intent to Use	USA	6/8/19	N/A
NON-REM AT THE WRONG TIME	87954324	N/A	Published (Pending) Intent to Use	USA	6/8/19	N/A
KNOW NARCOLEPSY	87830683	5588181	Registered	USA	3/12/18	10/16/18
HARMONY BIOSCIENCES	87759175	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A
HB	87759246	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A
HARMONY BIOSCIENCES						
HB	87759250	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A

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(iii) None.

Schedule 6.15(a)(2)

1. License Agreements

a. License and Commercialization Agreement, dated as of July 27, 2018, between Bioprojet and the Borrower, (a) as amended by that certain Amendment No. 1 to License and Commercialization Agreement, dated as of August 27, 2018, (b) as modified by that certain Limited Waiver of License and Commercialization Agreement, dated as of March 27, 2019 (as amended by (i) that certain Amendment to Limited Waiver of License and Commercialization Agreement, dated as of April 5, 2019 and (ii) that Second Amendment to Limited Waiver of License and Commercialization Agreement, dated as of April 9, 2019).

b. Trademark and License Agreement, dated as of August 2018 between Bioprojet and the Borrower.

2. Licenses Trademarks:

Licensee	Mark	Application/Registration Number	Application/Registration Date
Harmony Biosciences, LLC	WAKIX	4680400	03-Feb-2015
Harmony Biosciences, LLC	WAKIREM	5338731	21-Nov-2017

3. Licensed Patents:

Licensee	Patent No. and Issue Date		
Harmony Biosciences, LLC	8,207,197 / 26-Jun-2012		
Harmony Biosciences, LLC	8,354,430 / 15-Jan-2013		
Harmony Biosciences, LLC	8,486,947 / 16-Jul-2013		
Harmony Biosciences, LLC	7,169,928 / 30-Jan-2007		
Harmony Biosciences, LLC	7,910,605 / 22-Mar-2011		

SCHEDULE 6.15(j)

INFRINGEMENT NOTICES

MATERIAL AGREEMENTS AND KEY CONTRACTS

Agreement type	Holdings, Borrower or Subsidiary	Counterparty	Description	Effective Date
Services Agreement	Borrower	Symphony Health Solutions Corporation	Electronic data platform including: licensing data, data analysis & storage	1-May-2018
CRO Agreement	Borrower	PPD Development LLP	CRO services for clinical research program	20-Aug-2019
CRO Agreement	Borrower	Parexel International	CRO services for Expanded Access Program	03-Dec-2017
Master Services Agreement	Borrower	Synchrony Group	Marketing and advertising (Commercial)	13-Nov-2017 (new agreement to be executed Jan 2020)
Master Services Agreement	Borrower	Synchrony Group	Scientific and medical communications (Medical Affairs)	13-Nov-2017 (new agreement to be executed Jan 2020)
Master Services Agreement	Borrower	Zeno Group, Inc	Corporate communications and public relations agency	19-Dec-2019
Master Services Agreement	Borrower	Deerfield Agency, Inc.	Marketing and advertising	01-Jun-2018
Master Software License & Services Agreement(s)	Borrower	Accenture LLP	FDA submissions and support for Regulatory Affairs	14-May-2018
Master Services Agreement	Borrower	Evoke Group	Marketing and advertising (digital)	20-Sep-2018
Leasing & Services Agreement(s)	Borrower	Wheels LT	National fleet vehicle leasing and vehicle maintenance services	08-May-2018

TRANSACTIONS WITH AFFILIATES

- 1. The Paragon Management Agreements
- 2. Series A Preferred Stock Purchase Agreement, dated September 22, 2017, by and among Harmony Biosciences II, Inc. and the Purchasers named therein, as amended.
- 3. Preferred Stock Purchase Agreement, dated January 8, 2018, by and among Harmony Biosciences II, Inc. and the Purchasers named therein, as amended.
- 4. Series C Preferred Stock Purchase Agreement, dated August 9, 2018, by and among Harmony Biosciences II, Inc. and the Purchasers named therein, as amended.
- 5. Second Amended and Restated Voting Agreement, entered into as of August 9, 2019, by and among Harmony Biosciences II, Inc. and the other parties thereto, as amended.
- 6. Second Amended and Restated Investors Rights Agreement, dated as of August 9, 2019, by and among Harmony Biosciences II, Inc. and the other parties thereto, as amended.
- 7. Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of August 9, 2019, by and among Harmony Biosciences II, Inc. and the other parties thereto, as amended.

DEPOSIT AND DISBURSEMENT ACCOUNTS

[Account information]

<u>SCHEDULE 8.2(b)</u>

INDEBTEDNESS TO BE PAID

That certain Term Loan Agreement, dated as of February 28, 2019, among Holdings, Borrower and CRG Servicing LLC.

SCHEDULE 8.2(c)

EXISTING INDEBTEDNESS

SCHEDULE 8.3(c)

EXISTING LIENS

SCHEDULE 8.5(a)

INVESTMENTS

EXISTING AFFILIATE TRANSACTIONS

The Paragon Management Agreements, as in existence on the date hereof.

SCHEDULE 10.2

NOTICE INFORMATION

If to Holdings, the Borrower or any Subsidiary:

Harmony Biosciences, LLC
[Address]

and

Paragon Biosciences, LLC
[Address]

With a copy to (such copy shall not be deemed to constitute notice):

Address:

Katten Muchin Rosenman LLP
[Address]

If to Administrative Agent or any Lender:

OrbiMed Royalty & Credit Opportunities III, LP
[Address]

With a copy to (such copy shall not be deemed to constitute notice):

Address:

Covington & Burling LLP [Address]

EXHIBIT A FORM OF PROMISSORY NOTE

\$[●] [DATE]

FOR VALUE RECEIVED, HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), hereby promises to pay to [•], a [•] (together with its Affiliates, successors, transferees and assignees, the "<u>Holder</u>"), on the Maturity Date or as otherwise required under the Credit Agreement (as defined below) the principal sum of (a) [•] DOLLARS (\$[•]) or (b) in any case if less or more, the aggregate unpaid principal amount of the Loans made (or continued) by the Holder pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and between the Borrower, the Lenders party thereto and ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, as the Administrative Agent. Unless otherwise defined herein or the context otherwise requires, terms used in this Note have the meanings provided in the Credit Agreement.

The Borrower also promises to pay interest on the unpaid principal amount hereof from time to time outstanding from the date hereof until maturity (whether by acceleration or otherwise) and, after maturity upon demand, until paid in full, at the rates per annum and on the dates specified in the Credit Agreement, as well as any other amounts that may be due to the Holder upon maturity (whether by acceleration or otherwise) under or in respect of this Note pursuant to, and in accordance with, the terms of the Credit Agreement.

Pursuant to, and in accordance with, Section 3.2, Section 3.4 and Section 3.6 of the Credit Agreement, payments of both principal and interest are to be made by Borrower in U.S. Dollars in same day or immediately available funds to the account designated by the Holder pursuant to the Credit Agreement.

This Note is referred to in, and evidences Indebtedness incurred under, the Credit Agreement, to which reference is made for a description of the security and guarantee for this Note and for a statement of the terms and conditions on which the Borrower is permitted and required to make prepayments and repayments of the unpaid principal amount of the Indebtedness evidenced by this Note and on which such Indebtedness may be declared to be immediately due and payable. Any prepaid principal of this Note may not be reborrowed.

All parties hereto, whether as makers, endorsers or otherwise, severally waive presentment for payment, demand, protest and notice of dishonor.

THIS NOTE HAS BEEN ISSUED WITH ORIGINAL ISSUE DISCOUNT FOR U.S. FEDERAL INCOME TAX PURPOSES. REQUESTS FOR INFORMATION REGARDING THE ISSUE PRICE, AMOUNT OF ORIGINAL ISSUE DISCOUNT, ISSUE DATE AND YIELD TO MATURITY WITH RESPECT TO THIS NOTE MAY BE DIRECTED TO THE BORROWER CARE OF CHIEF FINANCIAL OFFICER OF HARMONY BIOSCIENCES, LLC AT 630 W GERMANTOWN PIKE, PLYMOUTH MEETING, PA 19462

THIS NOTE HAS BEEN DELIVERED IN NEW YORK, NEW YORK, AND SHALL BE DEEMED TO BE A CONTRACT MADE UNDER AND GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK).

[Signature Page Follows.]

Ву:	
	Name: Title:

HARMONY BIOSCIENCES, LLC

[Signature Page to Promissory Note]

$\frac{\text{EXHIBIT B}}{\text{FORM OF LOAN REQUEST}}$

[DATE]

OrbiMed Royalty & Credit Opportunities III, LP [Address]

Ladies and Gentlemen:

Reference is hereby made to that certain Credit Agreement, dated as of the date hereof (as amended, supplemented or otherwise modified from time to time and in effect on the date hereof, the "Credit Agreement"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "Borrower"), the Lenders party thereto, and ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership, as administrative agent (together with its, successors, transferees and assignees, the "Administrative Agent").

Unless otherwise defined herein or the context otherwise requires, terms used herein have the meanings provided in the Credit Agreement.

Pursuant to the provisions of Section 2.2 of the Credit Agreement, the Borrower hereby requests the Loans of \$200,000,000.00 to be made on the date hereof (the "<u>Proposed Disbursement Date</u>"), which Loans shall be evidenced by those certain Promissory Notes dated as of the date hereof, issued to the Lenders in the aggregate original principal amount of \$200,000,000.00.

The Borrower hereby represents and warrants to the Administrative Agent, for the benefit of the Secured Parties, that:

- (a) the proceeds of the proposed Loans are to be used for the purposes set forth in Section 8.17 of the Credit Agreement; and
- (b) bank account details and wire transfer instructions for disbursement of the proceeds of the proposed Loans are set forth on Schedule A hereto.

The Borrower hereby irrevocably authorizes and directs the Administrative Agent (or its sub-agent) to disburse the proceeds of the Loans requested hereby as set forth in <u>Schedule A</u> hereto.

The Borrower hereby agrees that the payments made in accordance with the wire transfer instructions set forth on <u>Schedule A</u> hereto are made for the administrative convenience of the Borrower and that the legal effect thereof is the same as if the proceeds of the Loans requested hereby were transferred directly to the Borrower by the Lenders and distributed by the Borrower.

The Borrower hereby acknowledges that the Administrative Agent (or its sub-agent) shall wire the amounts set forth on <u>Schedule A</u> hereto strictly on the basis of the information set forth on <u>Schedule A</u> hereto without making any investigation as to the accuracy thereof. In the event that any of such information is incorrect, the Borrower agrees that the Lenders and the Administrative Agent (and its sub-agent) shall not have any liability for any losses, costs, taxes, fees and expenses arising strictly therefrom.

The Borrower acknowledges that any amounts disbursed by the Administrative Agent pursuant to the instructions set forth below are made entirely on behalf of the Borrower; the Lenders and the Administrative Agent (or its sub-agent) will not be responsible for calculating taxes, reporting taxes or deducting withholding taxes owing in respect of such disbursements; and the Borrower will indemnify the Lenders and the Administrative Agent (and its sub-agent), pursuant to the Credit Agreement, for any withholding taxes owing on such disbursements.

The officer signing below is an Authorized Officer of the Borrower and is authorized to request the Loans contemplated hereby and issue this Loan Request on behalf of the Borrower.

[Signature Page Follows]

Very truly yours,
HARMONY BIOSCIENCES, LLC,
as the Borrower
Ву:
Name:
Title:
[Signature Page to Loan Request]

Schedule A

Disbursement / Wire Instructions

EXHIBIT C

FORM OF COMPLIANCE CERTIFICATE

HARMONY BIOSCIENCES, LLC

COMPUTATION DATE: , 2

This Compliance Certificate (this "Certificate") is delivered pursuant to [Section 5.7][Section 7.1(d)] of the Credit Agreement, dated as of January 9, 2020 (the "Credit Agreement"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "Borrower"), the Lenders party thereto and ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership, as administrative agent (together with its, successors, transferees and assignees, the "Administrative Agent"). Unless otherwise defined herein or the context otherwise requires, terms used in this Certificate have the meanings provided in the Credit Agreement.

This Certificate relates to the [Calendar Month][Fiscal Quarter][Fiscal Year] commencing on , 20 and ending on , 20 (such latter date being the "Computation Date").

The undersigned is duly authorized to execute and deliver this Certificate on behalf of the Borrower. By executing this Certificate, the undersigned hereby certifies to the Administrative Agent and each Lender that as of the Computation Date:

- (a) [Attached hereto as Annex I are the unaudited reports of (i) the Net Revenue for each Product for such calendar month and for the twelve-month period ending with the end of such calendar month, and including in comparative form the figures for the corresponding calendar month in the immediately preceding twelve-month period, (ii) the Liquidity of Borrower at the end of such calendar month and at the end of the corresponding calendar month in the preceding Fiscal Year, in comparative form, (iii) the number of employees of Holdings, the Borrower and its Subsidiaries as of the end of such period, including any changes thereto and (iv) prescription data of Holdings, the Borrower and its Subsidiaries with respect to each Product.]1
- (b) [Attached hereto as Annex [II] are [(i) the unaudited consolidated balance sheet of Holdings, Borrower and the Subsidiaries as of the end of such Fiscal Quarter and consolidated statements of income and cash flow of Holdings, the Borrower and the Subsidiaries for such Fiscal Quarter and for the period commencing at the end of the previous Fiscal Year and ending with the end of such Fiscal Quarter and (ii)]² the Net Revenue for each Product for such Fiscal Quarter and for the twelve-month period ended with the end of such Fiscal Quarter, and including in comparative form the figures for the corresponding Fiscal Quarter in the immediately preceding twelve-month period, all of which are complete and correct (subject to the absence of footnotes and normal year-end audit adjustments).]³

¹ INCLUDE ONLY FOR MONTHLY FINANCIAL DELIVERABLES

² INCLUDE ONLY FOR FIRST THREE FISCAL QUARTERS OF EACH FISCAL YEAR

³ INCLUDE FOR QUARTERLY FINANCIAL DELIVERABLES ONLY.

[Attached hereto as Annex [II] are (i) the consolidated balance sheet of Holdings, the Borrower and the Subsidiaries, and the related consolidated statements of income and cash flow of Holdings, the Borrower and the Subsidiaries for such Fiscal Year, setting forth in comparative form the figures for the immediately preceding Fiscal Year, audited (without any Impermissible Qualification) by independent public accountants reasonably acceptable to the Required Lenders and (ii) the Net Revenue for each Product for such Fiscal Year and including in comparative form the figures for the corresponding immediately preceding Fiscal Year.]4

- (c) [The financial statements delivered with this Certificate in accordance with Section 7.1(b) or (c) of the Credit Agreement, as applicable, fairly present in all material respects the financial condition of Holdings, the Borrower and the Subsidiaries (subject to the absence of footnotes and to normal year-end audit adjustments in the case of unaudited financial statements).]5
- (d) During such [Fiscal Quarter][Fiscal Year] and as of the Computation Date, Holdings, the Borrower and the Subsidiaries have at all times been in compliance in all respects with the financial covenant set forth in Section 8.4 of the Credit Agreement. Set forth on Attachment [1] hereto are calculations showing compliance with such financial covenant as of the Computation Date. 6
- (e) No Event of Default has occurred and is continuing[except as set forth on <u>Attachment [2]</u> hereto, which includes a description of the nature and period of existence of such Event of Default and what action Holdings, the Borrower or any of the Subsidiaries has taken, is taking or proposes to take with respect thereto]. ⁷
- (f) Subsequent to the date of the most recent Compliance Certificate submitted by the undersigned pursuant to Section 7.1(d) of the Credit Agreement prior to the date hereof in respect of Section 7.1(b) or (c), none of Holdings, the Borrower or any Subsidiary has formed or acquired any new Subsidiary[except as set forth on Attachment [3] hereto, in which case such new Subsidiary has complied with the requirements of Section 7.8 of the Credit Agreement]. 8
- (g) Subsequent to the date of the most recent Compliance Certificate submitted by the undersigned pursuant to Section 7.1(d) of the Credit Agreement prior to the date hereof in respect of Section 7.1(b) or (c), none of Holdings, the Borrower or any Subsidiary has acquired any real property[except as set forth on https://dx.doi.org/10.108/j.cc/ hereto, in which case the Borrower has complied with the requirements of Section 7.8 of the Credit Agreement with respect to such real property]. 9
- 4 INCLUDE FOR ANNUAL FINANCIAL DELIVERABLES ONLY.
- 5 INCLUDE ONLY FOR ANNUALS OR FIRST THREE FISCAL QUARTERS OF EACH FISCAL YEAR
- 6 INCLUDE FOR QUARTERLY AND ANNUAL FINANCIAL DELIVERABLES ONLY.
- 7 INCLUDE FOR QUARTERLY AND ANNUAL FINANCIAL DELIVERABLES ONLY.
- 8 INCLUDE FOR QUARTERLY AND ANNUAL FINANCIAL DELIVERABLES ONLY.
- 9 INCLUDE FOR QUARTERLY AND ANNUAL FINANCIAL DELIVERABLES ONLY.

- (h) [Attached hereto as Attachment [5] is a report listing (i) all Material Agreements and Key Contracts entered into during such Fiscal Quarter, (ii) all existing Material Agreements or Key Contracts amended or terminated during such Fiscal Quarter and (iii) all Permits, including all Regulatory Authorizations, issued to Holdings, the Borrower or any of the Subsidiaries during such Fiscal Quarter.]¹⁰
- (i) [Attached hereto as <u>Attachment [6]</u> is a report listing all applications for the registration of any Intellectual Property Collateral with the USPTO or any similar office or agency in any other country or any political subdivision thereof filed during such Fiscal Quarter.]¹¹

[Signature Page Follows]

 $^{^{10}}$ $\,$ INCLUDE FOR QUARTERLY FINANCIAL DELIVERABLES ONLY — TO BE DELIVERED ON A STANDALONE BASIS WHEN REQUIRED FOR THE FINAL QUARTER OF THE FISCAL YEAR.

¹¹ INCLUDE FOR QUARTERLY FINANCIAL DELIVERABLES ONLY.

IN WITNESS WHEREOF, the undersigned has caused this Certificate to be executed and delivered, and the certification and warranties contain
herein to be made, by its chief financial or accounting Authorized Officer as of the date first above written.

HADMONV	BIOSCIENCES.	TIC
HARMUNY	BIOSCIENCES.	LILC

Ву:		
	Name: Title:	

[Signature Page to Compliance Certificate]

Annex I

[Annex II]

[Attachment 1]

[Attachment 2]

[Attachment 3]

[Attachment 4]

[Attachment 5]

[Attachment 6]

EXHIBIT D

GUARANTEE

This GUARANTEE, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, this "<u>Guarantee</u>"), is made by Harmony Biosciences II, Inc., a Delaware corporation ("<u>Holdings</u>") (together with any additional Persons named pursuant to <u>Section 5.5</u> below, each, a "<u>Guarantor</u>", and collectively, the "<u>Guarantors</u>"), in favor of the Secured Parties (as defined below).

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among the Borrower, the Lenders party thereto, and OrbiMed Royalty & Credit Opportunities III, LP, a Delaware limited partnership, as administrative agent (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>"), the Lenders have extended a Commitment to make Loans to the Borrower; and

WHEREAS, as a condition precedent to the making of the Loans and as an inducement for the Lenders to make the Loans, in each case, under the Credit Agreement, the Guarantors are required to execute and deliver this Guarantee;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and in order to induce the Lenders to make the Loans to the Borrower, each Guarantor hereby agrees, for the benefit of the Secured Parties, as follows.

ARTICLE I DEFINITIONS

SECTION 1.1. <u>Certain Terms</u>. The following terms (whether or not underscored) when used in this Guarantee, including its preamble and recitals, shall have the following meanings (such definitions to be equally applicable to the singular and plural forms thereof):

"Administrative Agent" is defined in the first recital.

"Credit Agreement" is defined in the first recital.

"Guarantee" is defined in the preamble.

"Guarantor" is defined in the preamble.

"Holdings" is defined in the preamble.

"Obligor" is defined in Section 2.1(a).

"Secured Parties" means, collectively, the Administrative Agent and the Lenders, and "Secured Party" means any one of them.

SECTION 1.2. <u>Credit Agreement Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Guarantee, including its preamble and recitals, have the meanings provided in the Credit Agreement.

ARTICLE II GUARANTEE PROVISIONS

SECTION 2.1. Guarantee. Each Guarantor jointly and severally, absolutely, unconditionally and irrevocably:

- (a) guarantees the full and punctual payment when due, whether at stated maturity, by required prepayment, declaration, acceleration, demand or otherwise, and performance of all Obligations of the Borrower, Holdings and the other Guarantors (each, an "Obligor") now or hereafter existing, whether for principal, interest (including interest accruing at the then applicable Default rate as provided in Section 3.5 of the Credit Agreement, whether or not a claim for post-filing or post-petition interest is allowed under applicable Law following the institution of a proceeding under bankruptcy, insolvency or similar Laws), fees, expenses or otherwise (including all such amounts which would become due but for the operation of the automatic stay under Section 362(a) of the United States Bankruptcy Code, 11 U.S.C. §362(a), and the operation of Sections 502(b) and 506(b) of the United States Bankruptcy Code, 11 U.S.C. §502(b) and §506(b)); and
- (b) indemnifies and holds harmless each Secured Party solely to the extent required by (and subject to the limitations set forth in) Section 10.04 of the Credit Agreement with the references to the Borrower therein being changed to references to such Guarantor, *mutatis mutandis*;

provided that each Guarantor shall only be liable under this Guarantee for the maximum amount of such liability that can be hereby incurred without rendering this Guarantee, as it relates to such Guarantor, voidable under applicable Law relating to fraudulent conveyance or fraudulent transfer, and not for any greater amount. This Guarantee constitutes a guarantee of payment when due and not of collection, and each Guarantor specifically agrees that it shall not be necessary or required that the Secured Parties exercise any right, assert any claim or demand or enforce any remedy whatsoever against such Guarantor or any other Person before or as a condition to the obligations of such Guarantor becoming due hereunder.

SECTION 2.2. Reinstatement, Etc. Each Guarantor agrees that this Guarantee shall continue to be effective or be reinstated (including on or after the Termination Date), as the case may be, if at any time any payment (in whole or in part) of any of the Obligations is invalidated, declared to be fraudulent or preferential, set aside, rescinded or must otherwise be restored by any Secured Party, including upon the occurrence of any Event of Default set forth in Section 9.1(h) of the Credit Agreement or otherwise, all as though such payment had not been made.

SECTION 2.3. <u>Guarantee Absolute, Etc</u>. This Guarantee shall in all respects be a continuing, absolute, unconditional and irrevocable guarantee of payment, and shall remain in full force and effect until (unless reinstated pursuant to <u>Section 2.2</u> above) the Termination Date has occurred. Each Guarantor guarantees that the Obligations shall be paid strictly in accordance

with the terms of each Loan Document under which they arise, regardless of any Law, regulation or order now or hereafter in effect in any jurisdiction affecting any of such terms or the rights of the Secured Parties with respect thereto. The liability of each Guarantor under this Guarantee shall be absolute, unconditional and irrevocable irrespective of:

- (a) any lack of validity, legality or enforceability of any Loan Document;
- (b) the failure of any Secured Party (i) to assert any claim or demand or to enforce any right or remedy against such Guarantor or any other Person (including any other guarantor) under the provisions of any Loan Document or otherwise, or (ii) to exercise any right or remedy against any other guarantor (including such Guarantor and any other Guarantor) of, or collateral securing, any Obligations;
- (c) any change in the time, manner or place of payment of, or in any other term of, all or any part of the Obligations, or any other extension, compromise or renewal of any Obligation, or any amendment to, rescission, waiver, or other modification of, or any consent to or departure from, any of the terms of any Loan Document;
- (d) any reduction, limitation, impairment or termination of any Obligations for any reason, including any claim of waiver, release, surrender, alteration or compromise, and shall not be subject to (and each Guarantor hereby waives any right to or claim of) any defense or setoff, counterclaim, recoupment or termination whatsoever by reason of the invalidity, illegality, irregularity, compromise, unenforceability of, or any other event or occurrence affecting, any Obligations or otherwise, other than the defense that (i) payment has already been made to and received by the Secured Party and (ii) payment is not yet due and payable (the "Permissible Defenses");
- (e) any addition, exchange or release of any collateral or of any Person that is (or will become) a guarantor of the Obligations, or any surrender or non-perfection of any collateral, or any amendment to, or waiver or release of, or addition to, or consent to or departure from, any other guarantee held by the Secured Parties securing any of the Obligations; or
- (f) any other circumstance which might otherwise constitute a defense (other than the Permissible Defenses) available to, or a legal or equitable discharge of, any Obligor, any surety or any guarantor (including any Guarantor).

SECTION 2.4. <u>Setoff</u>. Each Guarantor hereby irrevocably authorizes each Secured Party, without the requirement that any notice be given to such Guarantor (such notice being expressly waived by such Guarantor), upon the occurrence and during the continuance of any Event of Default, to appropriate and apply to the payment of the Obligations owing to it (whether or not then due), and (as security for such Obligations) each Guarantor hereby grants to each Secured Party a continuing security interest in, any and all balances, credits, deposits, accounts or moneys of such Guarantor then or thereafter maintained with or on behalf of such Secured Party. Each Secured Party agrees to notify such Guarantor after any such set-off and application made by such Secured Party; <u>provided</u> that the failure to give such notice shall not affect the validity of such setoff and application. The rights of the Secured Parties under this <u>Section 2.4</u> are in addition to other rights and remedies (including other rights of setoff under applicable Law or otherwise) which the Secured Parties may have.

SECTION 2.5. <u>Waiver, Etc</u>. Each Guarantor waives promptness, diligence, notice of acceptance and any other notice with respect to any of the Obligations and this Guarantee and any requirement that the Secured Parties protect, secure, perfect or insure any Lien, or any property subject thereto, or exhaust any right or take any action against any Obligor or any other Person (including any Guarantor) or entity or any collateral securing the Obligations, as the case may be.

SECTION 2.6. <u>Postponement of Subrogation, Etc.</u> Each Guarantor agrees that it will not exercise any rights which it may acquire by way of rights of subrogation under any Loan Document to which it is a party, nor shall such Guarantor seek or be entitled to seek any contribution or reimbursement from the Borrower or any other Obligor or Guarantor, in respect of any payment made under any Loan Document or otherwise, until following the Termination Date. Any amount paid to such Guarantor on account of any such subrogation rights prior to the Termination Date shall be held in trust for the benefit of the Secured Parties and shall immediately be paid and turned over to the Administrative Agent, for the benefit of the Secured Parties, in the exact form received by such Guarantor (duly endorsed in favor of the Administrative Agent, if required), to be credited and applied against the Obligations, whether matured or unmatured, in accordance with <u>Section 2.7</u>; <u>provided</u> that, if such Guarantor has made payment to the Administrative Agent of all or any part of the Obligations and the Termination Date has occurred, then, at such Guarantor's request, the Administrative Agent will, at the expense of such Guarantor, execute and deliver to such Guarantor appropriate documents (without recourse and without representation or warranty) necessary to evidence the transfer by subrogation to such Guarantor of an interest in the Obligations resulting from such payment. In furtherance of the foregoing, at all times prior to the Termination Date, such Guarantor shall refrain from taking any action or commencing any proceeding against the Borrower or any other Obligor or Guarantor (or their successors or assigns, whether in connection with a bankruptcy proceeding or otherwise) to recover any amounts in respect of payments made under this Guarantee to the Administrative Agent.

SECTION 2.7. <u>Payments; Application</u>. Each Guarantor agrees that all obligations of such Guarantor hereunder shall be paid solely in U.S. Dollars to the Administrative Agent and the Lenders in immediately available funds, without set-off, counterclaim or other defense and in accordance with the Credit Agreement, including Article III, Article IV and Article X thereof, free and clear of and without deduction for any Non-Excluded Taxes, such Guarantor hereby agreeing to comply with and be bound by the provisions of the Credit Agreement in respect of all payments and application of such payments made by it hereunder, including Article III, Article IV and Article X thereof, and the provisions of which Articles and Sections are hereby incorporated into and made a part of this Guarantee by this reference as if set forth herein; <u>provided</u> that references to the "Borrower" in such Articles and Sections shall be deemed to be references to such Guarantor, and references to "this Agreement" in such Articles and Sections shall be deemed to be references to this Guarantee.

ARTICLE III REPRESENTATIONS AND WARRANTIES

In order to induce the Secured Parties to enter into the Credit Agreement and make the Loans thereunder, each Guarantor represents and warrants to the Administrative Agent, for the benefit of the Secured Parties, as set forth below.

SECTION 3.1. <u>Credit Agreement Representations and Warranties</u>. The representations and warranties contained in Article VI of the Credit Agreement, insofar as the representations and warranties contained therein are applicable to such Guarantor and its properties, are true and correct in all material respects as of the Closing Date, with each such representation and warranty set forth in such Article VI of the Credit Agreement (insofar as applicable as aforesaid) and all other terms of the Credit Agreement to which reference is made therein, together with all related definitions and ancillary provisions, being hereby incorporated into this Guarantee by this reference as though specifically set forth in this <u>Article III</u>.

SECTION 3.2. Financial Condition, Etc. Each Guarantor has knowledge of the Borrower's and each other Guarantor's financial condition and affairs and has adequate means to obtain from each such Person on an ongoing basis information relating thereto and to each such Person's ability to pay and perform the Obligations, and agrees to assume the responsibility for keeping, and to keep, so informed for so long as this Guarantee is in effect. Each Guarantor acknowledges and agrees that the Secured Parties shall have no obligation to investigate the financial condition or affairs of the Borrower or any other Guarantor for the benefit of such Guarantor nor to advise such Guarantor of any fact respecting, or any change in, the financial condition or affairs of each such Person that might become known to the Secured Parties at any time, whether or not the Secured Parties know or believe or have reason to know or believe that any such fact or change is unknown to such Guarantor, or might (or does) materially increase the risk of such Guarantor as guarantor, or might (or would) affect the willingness of such Guarantor to continue as a guarantor of the Obligations.

SECTION 3.3. <u>Best Interests</u>. It is in the best interests of each Guarantor to execute this Guarantee inasmuch as each Guarantor will, as a result of being an Affiliate of the Borrower, derive substantial direct and indirect benefits from the Loans made to the Borrower by the Lenders pursuant to the Credit Agreement, and each Guarantor agrees that the Lenders are relying on this representation in agreeing to make the Loans to the Borrower.

ARTICLE IV COVENANTS, ETC.

SECTION 4.1. <u>Covenants</u>. Each Guarantor covenants and agrees that, at all times prior to the Termination Date, it will perform, comply with and be bound by all of the agreements, covenants and obligations contained in the Credit Agreement (including Articles VII and VIII of the Credit Agreement) which are applicable to such Guarantor or its properties, with each such agreement, covenant and obligation contained in the Credit Agreement and all other terms of the Credit Agreement to which reference is made in this <u>Article IV</u>, together with all related definitions and ancillary provisions, being hereby incorporated into this Guarantee by this reference as though specifically set forth in this <u>Article IV</u>.

ARTICLE V MISCELLANEOUS PROVISIONS

SECTION 5.1. <u>Loan Document</u>. This Guarantee is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.

SECTION 5.2. <u>Binding on Successors, Transferees and Assigns; Assignment</u>. This Guarantee shall remain in full force and effect until the Termination Date has occurred, shall be binding upon each Guarantor and its successors, transferees and assigns and shall inure to the benefit of and be enforceable by the Secured Parties; <u>provided</u> that such Guarantor may not (unless otherwise permitted under the terms of the Credit Agreement) assign any of its obligations hereunder without the prior written consent of the Secured Parties. Without limiting the generality of the foregoing, to the extent permitted by the Credit Agreement, a Lender may assign or otherwise transfer (in whole or in part) its Commitment, Note or Loans held by it to any other Person, and such other Person shall thereupon become vested with all rights and benefits in respect thereof granted to that Lender under each Loan Document (including this Guarantee) or otherwise.

SECTION 5.3. <u>Amendments, Etc.</u> No amendment to or waiver of any provision of this Guarantee, nor consent to any departure by any Guarantor from its obligations under this Guarantee, shall in any event be effective unless the same shall be in writing and signed by the Administrative Agent and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

SECTION 5.4. <u>Notices</u>. All notices and other communications provided for hereunder shall be given or made as set forth in Section 10.2 of the Credit Agreement.

SECTION 5.5. <u>Additional Guarantors</u>. Upon the execution and delivery by any other Person of a supplement in the form of <u>Annex I</u> hereto, such Person shall become a "Guarantor" hereunder with the same force and effect as if it were originally a party to this Guarantee and named as a "Guarantor" hereunder. The execution and delivery of such supplement shall not require the consent of any other Guarantor hereunder, and the rights and obligations of each Guarantor hereunder shall remain in full force and effect notwithstanding the addition of any new Guarantor as a party to this Guarantee.

SECTION 5.6. No Waiver; Remedies. In addition to, and not in limitation of, Section 2.3 and Section 2.5, no failure on the part of any Secured Party to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right hereunder preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by Law.

SECTION 5.7. <u>Further Assurances</u>. Each Guarantor agrees, upon the written request of the Administrative Agent, to execute and deliver to the Secured Parties, from time to time, any additional instruments or documents deemed to be reasonably necessary by the Administrative Agent to cause this Guarantee to be, become or remain valid and effective in accordance with its terms.

SECTION 5.8. <u>Section Captions</u>. Section captions used in this Guarantee are for convenience of reference only and shall not affect the construction of this Guarantee.

SECTION 5.9. <u>Severability</u>. Any provision of this Guarantee which is prohibited or unenforceable in any jurisdiction shall, as to such provision and such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of this Guarantee or affecting the validity or enforceability of such provision in any other jurisdiction.

SECTION 5.10. Governing Law, Entire Agreement, Etc. THIS GUARANTEE AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS GUARANTEE OR ANY OTHER LOAN DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Guarantee, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter hereof and supersedes any prior agreements, written or oral, with respect hereto.

SECTION 5.11. Forum Selection and Consent to Jurisdiction. ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, THIS GUARANTEE, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE SECURED PARTIES OR ANY GUARANTOR IN CONNECTION HEREWITH SHALL BE BROUGHT AND MAINTAINED IN THE COURTS OF THE BOROUGH OF MANHATTAN IN THE CITY OF NEW YORK IN THE STATE OF NEW YORK OR IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK; PROVIDED THAT ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT THE ADMINISTRATIVE AGENT'S OR THE LENDERS' OPTION, IN THE COURTS OF ANY JURISDICTION WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND. THE SECURED PARTIES, BY ACCEPTANCE OF THIS GUARANTEE, AND EACH GUARANTOR IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF NEW YORK AT THE ADDRESS FOR NOTICES SPECIFIED IN SECTION 10.2 OF THE CREDIT AGREEMENT. THE SECURED PARTIES, BY ACCEPTANCE OF THIS GUARANTEE, AND EACH GUARANTOR HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY HAVE OR HEREAFTER MAY HAVE TO THE LAYING OF VENUE OF ANY SUCH LITIGATION BROUGHT IN ANY SUCH COURT REFERRED TO ABOVE AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM. TO THE EXTENT THAT THE SECURED PARTIES, BY ACCEPTANCE OF THIS

GUARANTEE, OR ANY GUARANTOR HAS OR HEREAFTER MAY ACQUIRE ANY IMMUNITY FROM JURISDICTION OF ANY COURT OR FROM ANY LEGAL PROCESS (WHETHER THROUGH SERVICE OR NOTICE, ATTACHMENT PRIOR TO JUDGMENT, ATTACHMENT IN AID OF EXECUTION OR OTHERWISE) WITH RESPECT TO ITSELF OR ITS PROPERTY, THE SECURED PARTIES, BY ACCEPTANCE OF THIS GUARANTEE, AND SUCH GUARANTOR, EACH ON ITS OWN BEHALF, HEREBY IRREVOCABLY WAIVES TO THE FULLEST EXTENT PERMITTED BY LAW SUCH IMMUNITY IN RESPECT OF ITS OBLIGATIONS UNDER THIS GUARANTEE.

SECTION 5.12. <u>Counterparts</u>. This Guarantee may be executed by the parties hereto in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. This Guarantee shall become effective when counterparts hereof executed on behalf of each Guarantor shall have been received by the Secured Parties. Delivery of an executed counterpart of a signature page to this Guarantee by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Guarantee.

SECTION 5.13. Waiver of Jury Trial. THE SECURED PARTIES, BY ACCEPTANCE OF THIS GUARANTEE, AND EACH GUARANTOR HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVE TO THE FULLEST EXTENT PERMITTED BY LAW ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, THIS GUARANTEE, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF ANY SECURED PARTY OR ANY GUARANTOR IN CONNECTION HEREWITH. EACH GUARANTOR ACKNOWLEDGES AND AGREES THAT IT HAS RECEIVED FULL AND SUFFICIENT CONSIDERATION FOR THIS PROVISION (AND EACH OTHER PROVISION OF EACH OTHER LOAN DOCUMENT TO WHICH IT IS A PARTY) AND THAT THIS PROVISION IS A MATERIAL INDUCEMENT FOR THE SECURED PARTIES TO ENTER INTO THE LOAN DOCUMENTS.

[Signature Page Follows]

IN WITNESS V	WHEREOF, each Guarantor	has caused this C	Guarantee to be duly	executed and d	lelivered by its A	Authorized O	fficer as of	the date
first above written.								

Н	ARMONY BIOSCIENCES II, INC.
В	y:
	Name:

Title:

[Signature Page to Guarantee]

SUPPLEMENT TO GUARANTEE

This SUPPLEMENT, dated as of , (this "<u>Supplement</u>"), is to the Guarantee, dated as of January 9, 2020 (as amended, supplemented, amended and restated or otherwise modified from time to time, the "<u>Guarantee</u>"), by the Guarantors (such term, and other terms used in this Supplement, to have the meanings set forth in Article I of the Guarantee, unless otherwise defined herein or if the context otherwise requires) from time to time party thereto, in favor of the Secured Parties (as defined in the Guarantee).

WITNESSETH:

WHEREAS, pursuant to a Credit Agreement, dated as of January 9, 2020 (as amended, supplemented, or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders party thereto and ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership, as administrative agent (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>"), the Lenders have extended a Commitment to make the Loans to the Borrower; and

WHEREAS, pursuant to the provisions of Section 5.5 of the Guarantee, each of the undersigned is becoming a Guarantor under the Guarantee; and

WHEREAS, each of the undersigned desires to become a "Guarantor" under the Guarantee in order to induce the Lenders to continue to extend the Loans under the Credit Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the undersigned agrees, for the benefit of the Secured Parties, as follows.

SECTION 1. <u>Party to Guarantee</u>, <u>Etc</u>. In accordance with the terms of the Guarantee, by its signature below, each of the undersigned hereby irrevocably agrees to become a Guarantor under the Guarantee with the same force and effect as if it were an original signatory thereto and each of the undersigned hereby (a) agrees to be bound by and comply with all of the terms and provisions of the Guarantee applicable to it as a Guarantor and (b) represents and warrants that the representations and warranties made by it as a Guarantor thereunder are true and correct as of the date hereof, unless stated to relate solely to an earlier date, in which case such representations and warranties shall be true and correct as of such earlier date. In furtherance of the foregoing, each reference to a "Guarantor" or "Guarantors" in the Guarantee shall be deemed to include each of the undersigned.

SECTION 2. <u>Representations</u>. Each of the undersigned hereby represents and warrants that this Supplement has been duly authorized, executed and delivered by it and that this Supplement and the Guarantee constitute its legal, valid and binding obligation, enforceable against it in accordance with its terms.

SECTION 3. <u>Full Force of Guarantee</u>. Except as expressly supplemented hereby, the Guarantee shall remain in full force and effect in accordance with its terms.

SECTION 4. <u>Severability</u>. Wherever possible each provision of this Supplement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Supplement shall be prohibited by or invalid under such Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Supplement or the Guarantee.

SECTION 5. Governing Law, Entire Agreement, Etc. THIS SUPPLEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR ANY DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Supplement, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter thereof and supersedes any prior agreements, written or oral, with respect thereto.

SECTION 6. <u>Effectiveness</u>. This Supplement shall become effective with respect to a Guarantor when a counterpart hereof executed by such undersigned Guarantor shall have been received by the Secured Parties. Delivery of an executed counterpart of a signature page to this Supplement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Supplement.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the parties hereto has caused this Supplement to the date first above written.	be duly executed and delivered by its Authorized Officer as of
	[NAME OF ADDITIONAL SUBSIDIARY]
	Ву:
	Name:
	Title:
	[NAME OF ADDITIONAL SUBSIDIARY]
	Ву:

Name: Title:

[Signature Page to Guarantee Supplement]

EXHIBIT E PLEDGE AND SECURITY AGREEMENT

This PLEDGE AND SECURITY AGREEMENT, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, this "Security Agreement"), is made by HARMONY BIOSCIENCES LLC, a Delaware limited liability company (the "Borrower"), HARMONY BIOSCIENCES II, INC., a Delaware corporation, ("Holdings") (the Borrower and Holdings, together with any other entity that may become a party hereto as provided herein, are referred to each as a "Grantor" and, collectively as the "Grantors"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, as Administrative Agent (the "Administrative Agent") for the Secured Parties (defined below).

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among the Borrower, the Lenders party thereto and the Administrative Agent, the Lenders have extended a Commitment to make Loans to the Borrower; and

WHEREAS, as a condition precedent to the making of the Loans and as an inducement for the Lenders to make the Loans, in each case, under the Credit Agreement, each Grantor is required to execute and deliver this Security Agreement;

WHEREAS, it is required under the terms of the Credit Agreement that the Grantors shall have granted, pledged and assigned the security interests and undertaken the obligations contemplated by this Security Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Grantor agrees, for the benefit of the Secured Parties, as follows:

ARTICLE I DEFINITIONS

SECTION 1.1. <u>Certain Terms</u>. The following terms (whether or not underscored) when used in this Security Agreement, including its preamble and recitals, shall have the following meanings (such definitions to be equally applicable to the singular and plural forms thereof):

"Administrative Agent" is defined in the preamble.

"Bioprojet Agreements" means the Key Contracts listed in clauses (a) through (b) of the definition thereof as of the date hereof, including any replacement thereof.

"Borrower" is defined in the preamble.

"Collateral" is defined in Section 2.1.

"Collateral Accounts" is defined in Section 4.3(b).

"Computer Hardware and Software Collateral" means (a) all of the Grantors' owned computer and other electronic data processing hardware, integrated computer systems, central processing units, memory units, display terminals, printers, features, computer elements, card readers, tape drives, hard and soft disk drives, cables, electrical supply hardware, generators, power equalizers, accessories and all peripheral devices and other related computer hardware, including all operating system software, utilities and application programs in whatsoever form; (b) all software programs (including both source code, object code and all related applications and data files) designed for use on the computers and electronic data processing hardware described in clause (a) above; (c) all firmware associated therewith; (d) all documentation (including flow charts, logic diagrams, manuals, guides, specifications, training materials, charts and pseudo codes) with respect to such hardware, software and firmware described in the preceding clauses (a) through (c); and (e) all rights with respect to all of the foregoing, including copyrights, licenses, options, warranties, service contracts, program services, test rights, maintenance rights, support rights, improvement rights, renewal rights and indemnifications and any substitutions, replacements, improvements, error corrections, updates, additions or model conversions of any of the foregoing.

"Control Agreement" means an authenticated record in form and substance reasonably satisfactory to the Administrative Agent, that provides for the Administrative Agent to have "control" (as defined in the UCC) over certain Collateral.

"Copyright Collateral" means all Copyrights, including: (a) the Copyrights referred to in Item A of Schedule V, and registrations and recordings thereof and all applications for registration thereof, whether pending or in preparation; (b) all Copyright licenses, including each material Copyright license referred to in Item B of Schedule V; (c) the right to sue for past, present and future infringements of any of the foregoing, all rights corresponding thereto, all extensions and renewals of any thereof; and (d) all Proceeds of the foregoing, including licenses, royalties, income, payments, claims, damages and Proceeds of suit, which are owned or licensed by the Grantors.

"Credit Agreement" is defined in the first recital.

"<u>Distributions</u>" means all dividends paid on Capital Securities, liquidating dividends paid on Capital Securities, shares (or other designations) of Capital Securities resulting from (or in connection with the exercise of) stock splits, reclassifications, warrants, options, non-cash dividends, mergers, consolidations, and all other distributions (whether similar or dissimilar to the foregoing) on or with respect to any Capital Securities constituting Collateral.

"Financing Statements" is defined in Section 3.7(b).

"General Intangibles" means all "general intangibles" and all "payment intangibles", each as defined in the UCC and shall include all interest rate or currency protection or hedging arrangements, all tax refunds, all licenses, permits, concessions and authorizations and all Intellectual Property Collateral (in each case, regardless of whether characterized as general intangibles under the UCC).

"Grantor" and "Grantors" are defined in the preamble.

"Holdings" is defined in the preamble.

"Intellectual Property Collateral" means, collectively, the Computer Hardware and Software Collateral, the Copyright Collateral, the Patent Collateral, the Trademark Collateral and the Trade Secrets Collateral.

"Intercompany Note" means any promissory note evidencing loans made by any Grantor to any other Grantor.

"Investment Property" means, collectively, (a) all "investment property" as such term is defined in Section 9-102(a)(49) of the UCC and (b) whether or not constituting "investment property" as so defined, all Pledged Notes.

"Motor Vehicles" means motor vehicles, tractors, trailers and other like property, if the title thereto is governed by a certificate of title or ownership.

"Patent Collateral" means:

- (a) all of the Patents, including all Patent applications in preparation for filing and each Patent and Patent application referred to in Item A of Schedule III;
- (b) all Patent licenses, and other agreements providing any Grantor with the right to use any items of the type referred to in clause(a) above, including each Patent license referred to in Litem B of Schedule III (excluding any licenses to any Grantor for commercially available off-the-shelf software); and
- (c) all Proceeds of, and rights associated with, the foregoing (including licenses, royalties income, payments, claims, damages and Proceeds of infringement suits) and the right to sue third parties for past, present or future infringements of any Patent and for breach or enforcement of any patent license.

"Permitted Liens" means all Liens permitted by Section 8.3 of the Credit Agreement.

"<u>Pledged Notes</u>" means all promissory notes listed on <u>Item J</u> of <u>Schedule II</u> (as such schedule may be amended or supplemented from time to time), all Intercompany Notes at any time issued to any Grantor and all other promissory notes issued to or held by any Grantor.

"Secured Parties" means, collectively, the Administrative Agent and the Lenders and

"Secured Party" means any one of them.

"Securities Act" is defined in Section 6.2(a).

"Security Agreement" is defined in the preamble.

"Trade Secrets" is defined in the definition of "Trade Secrets Collateral."

"<u>Trade Secrets Collateral</u>" means (a) all of the Grantors' common Law and statutory trade secrets and all other confidential and proprietary information, and all know-how obtained by or

used in the business of any Grantor (all of the foregoing being collectively called a "<u>Trade Secret</u>"), whether or not such Trade Secret has been reduced to a writing or other tangible form, including all documents and things embodying, incorporating or referring in any way to such Trade Secret; (b) all Trade Secret licenses, including each Trade Secret license referred to in <u>Schedule VI</u> (excluding any licenses to any Grantor for commercially available off-the-shelf software); and (c) including the right to sue for and to enjoin and to collect damages for the actual or threatened misappropriation of any Trade Secret and for the breach or enforcement of any such Trade Secret license.

"Trademark Collateral" means:

- (a) (i) all of the Grantors' Trademarks and all goodwill of the business associated therewith, now existing or hereafter adopted or acquired including those referred to in Item A of Schedule IV, whether currently in use or not, all registrations and recordings thereof and all applications in connection therewith, whether pending or in preparation for filing, including registrations, recordings and applications in the United States Patent and Trademark (the "USPTO") or in any office or agency of the United States of America, or any state thereof or any other country or political subdivision thereof or otherwise, and all common-law rights relating to the foregoing, and (ii) the right to obtain all reissues, extensions or renewals of the foregoing;
- (b) all Trademark licenses for the grant by or to any Grantors of any right to use any Trademark, including each Trademark license referred to in <u>Item B</u> of <u>Schedule IV</u> (excluding any licenses to any Grantor for commercially available off-the-shelf software);
- (c) the right to sue third parties for past, present and future infringements of any Trademark Collateral described in <u>clause (a)</u> and, to the extent applicable, <u>clause (b)</u>; and
- (d) all Proceeds of, and rights associated with, the foregoing, including any claim by any Grantor against third parties for past, present or future infringement or dilution of any Trademark, Trademark registration or Trademark license, or for any injury to the goodwill associated with the use of any such Trademark or for breach or enforcement of any Trademark license and all rights corresponding thereto throughout the world.
- SECTION 1.2. <u>Credit Agreement Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Security Agreement, including its preamble and recitals, have the meanings provided in the Credit Agreement.
- SECTION 1.3. <u>UCC Definitions</u>. When used herein the terms "Account", "Certificated Securities", "Chattel Paper", "Commercial Tort Claim", "Commodity Account", "Commodity Contract", "Deposit Account", "Document", "Electronic Chattel Paper", "Equipment", "Goods", "Instrument", "Inventory", "Letter of Credit Rights", "Payment Intangibles", "Proceeds", "Promissory Notes", "Securities Account", "Security Entitlement", "Supporting Obligations" and "Uncertificated Securities" have the meaning provided in Article 8 or Article 9, as applicable, of the UCC. "Letters of Credit" has the meaning provided in Section 5-102 of the UCC.

ARTICLE II SECURITY INTEREST

SECTION 2.1. <u>Grant of Security Interest</u>. Each Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of such Grantor's right, title and interest in and to the following property, whether now or hereafter existing, owned or acquired by such Grantor, and wherever located (collectively, the "<u>Collateral</u>"):

- (a) Accounts;
- (b) Chattel Paper;
- (c) Commercial Tort Claims, including those listed on <u>Item I</u> of <u>Schedule II</u> (as such schedule may be amended or supplemented from time to time);
 - (d) Deposit Accounts;
 - (e) Documents;
 - (f) General Intangibles;
 - (g) Goods (including Goods held on consignment with third parties);
 - (h) Instruments;
 - (i) Investment Property;
 - (j) Letter of Credit Rights and Letters of Credit;
 - (k) Supporting Obligations;
- (l) all books, records, writings, databases, information and other property relating to, used or useful in connection with, evidencing, embodying, incorporating or referring to, any of the foregoing in this <u>Section 2.1</u>;
- (m) all Proceeds of any of the foregoing and, to the extent not otherwise included, (i) all payments under insurance (whether or not the Administrative Agent is the loss payee thereof) in respect of Collateral and (ii) all tort claims; and
 - (n) all other property and rights of every kind and description and interests therein.

Notwithstanding anything to the contrary, the term "Collateral" shall not include:

(i) any General Intangibles or other rights, in each case arising under any contracts, instruments, lease, licenses or other documents as to which the grant of a security interest would (A) constitute or result in a violation, breach, termination, default or invalidity thereunder or thereof in favor of a third party, unless and until any required consents shall have been obtained or (B) give any other party to such contract, instrument, license or other document the right to terminate its obligations thereunder, including any Key Contract or Material Agreement to the extent described in this clause (i);

- (ii) Trademark applications filed in the USPTO on the basis of such Grantor's "intent to use" such trademark, unless and until acceptable evidence of use of the Trademark has been filed with the USPTO pursuant to Section 1(c) or Section 1(d) of the Lanham Act (15 U.S.C. 1051, et seq.), to the extent that granting a Lien in such Trademark application prior to such filing would adversely affect the enforceability or validity of such Trademark application;
- (iii) any asset, the granting of a security interest in which would be void, materially restricted or illegal under any applicable Law (including, without limitation, any requirement made under applicable Law to obtain the consent or approval of any Governmental Authority), or pursuant thereto would result in, or permit the termination of, such asset; or
- (iv) any asset subject to a Permitted Lien (other than Liens in favor of the Secured Parties) securing obligations permitted under the Credit Agreement to the extent that the grant of other Liens on such asset (A) would result in a breach, termination, invalidity or violation of, or constitute a default under, the agreement or instrument governing such Permitted Lien (or the transaction or obligations secured thereby), (B) would result in the loss of use of such asset or (C) would permit the holder of such Permitted Lien to terminate the Grantor's use of such asset;
 - (v) the Excluded Accounts, as that term is defined in Section 7.13 of the Credit Agreement;
- (vi) any assets with respect to which the Administrative Agent determines, in its reasonable discretion, that the cost of obtaining a security interest therein, or Lien thereon exceed the practical benefits to the Secured Parties of the security afforded thereby;
 - (vii) any leasehold or subleasehold interests in any real property; and
 - (viii) any Motor Vehicles.

provided that the property described in each of <u>clauses (i)</u>, (iii) and (iv) above shall only be excluded from the term "Collateral" to the extent the conditions stated in such clauses are not rendered ineffective pursuant to Sections 9-406, 9-407, 9-408 or 9-409 of the UCC or any other applicable Law;

<u>provided further</u> that the property described in each of <u>clauses (i)</u> through <u>(vii)</u> above shall not include any Proceeds, products, substitutions or replacements thereof (unless such Proceeds, products, substitutions or replacements would otherwise constitute property described in any of <u>clauses (i)</u> through <u>(vii)</u> above).

SECTION 2.2. <u>Security for Obligations</u>. This Security Agreement and the Collateral in which the Administrative Agent, for the benefit of the Secured Parties, is granted a security interest hereunder by the Grantors to secure the payment and performance of all of the Obligations.

SECTION 2.3. Grantors Remain Liable. Anything herein to the contrary notwithstanding:

- (a) the Grantors will remain liable under the contracts and agreements included in the Collateral to the extent set forth therein, and will perform all of their duties and obligations under such contracts and agreements to the same extent as if this Security Agreement had not been executed;
- (b) the exercise by any Secured Party of any of its rights hereunder will not release any Grantor from any of its duties or obligations under any such contracts or agreements included in the Collateral; and
- (c) the Secured Parties will not have any obligation or liability under any contracts or agreements included in the Collateral by reason of this Security Agreement, nor will the Secured Parties be obligated to perform any of the obligations or duties of any Grantor thereunder or to take any action to collect or enforce any claim for payment assigned hereunder.
- SECTION 2.4. <u>Distributions on Capital Securities</u>; <u>Payments on Pledged Notes</u>. In the event that any (a) Distribution with respect to any Capital Securities or (b) payment with respect to any Pledged Notes, in each case pledged hereunder, is not prohibited under Section 8.6 of the Credit Agreement, such Distribution or payment may be paid directly to the applicable Grantor. If any Distribution or payment is made in contravention of Sections 8.5 or 8.6 of the Credit Agreement, such Grantor shall hold the same segregated and in trust for the Administrative Agent, for the benefit of the Secured Parties, until paid to the Administrative Agent in accordance with <u>Section 4.1.5</u>.
- SECTION 2.5. Security Interest Absolute, Etc. This Security Agreement shall in all respects be a continuing, absolute, unconditional and irrevocable grant of security interest and shall remain in full force and effect, in each case, until the Termination Date. All rights of the Secured Parties and the security interests granted to the Administrative Agent, for the benefit of the Secured Parties, hereunder, and all obligations of the Grantors hereunder, shall, to the fullest extent permitted by applicable Law, in each case, be absolute, unconditional and irrevocable irrespective of:
 - (a) any lack of validity, legality or enforceability of any Loan Document (other than this Security Agreement);
- (b) the failure of any Secured Party (i) to assert any claim or demand or to enforce any right or remedy against the Borrower, Holdings or any of the Subsidiaries or any other Person (including any other Grantor) under the provisions of any Loan Document or otherwise, or (ii) to exercise any right or remedy against any other guarantor (including any other Grantor) of, or Collateral securing, any Obligations;
- (c) any change in the time, manner or place of payment of, or in any other term of, all or any part of the Obligations, or any other extension, compromise or renewal of any Obligations;
- (d) any reduction, limitation, impairment or termination of any Obligations for any reason, including any claim of waiver, release, surrender, alteration or compromise and shall not be subject to (and each Grantor hereby waives, until payment of all Obligations, any right to or claim of) any defense or setoff, counterclaim, recoupment or termination whatsoever by reason of the invalidity, illegality, nongenuineness, irregularity, compromise, unenforceability of, or any other event or occurrence affecting, any Obligations or otherwise;

- (e) any amendment to, rescission, waiver, or other modification of, or any consent to or departure from, any of the terms of any Loan Document;
- (f) any addition, exchange or release of any Collateral or of any Person that is (or will become) a Grantor (including the Grantors hereunder), or any surrender or non-perfection of any Collateral, or any amendment to or waiver or release or addition to, or consent to or departure from, any other guaranty held by the Administrative Agent, for the benefit of the Secured Parties, securing any of the Obligations; or
- (g) any other circumstance which might otherwise constitute a defense available to, or a legal or equitable discharge of the Borrower, Holdings or any of the Subsidiaries, any surety or any guarantor.

SECTION 2.6. <u>Postponement of Subrogation</u>. Each Grantor agrees that it will not exercise any rights against another Grantor which it may acquire by way of rights of subrogation under any Loan Document to which it is a party until following the Termination Date. No Grantor shall seek or be entitled to seek any contribution or reimbursement from the Borrower, Holdings or any other Grantor, in respect of any payment made under any Loan Document or otherwise, until following the Termination Date. Any amount paid to any Grantor on account of any such subrogation rights prior to the Termination Date shall be held in trust for the benefit of the Secured Parties and shall immediately be paid and turned over to the Administrative Agent, for the benefit of the Secured Parties, in the exact form received by such Grantor (duly endorsed in favor of the Administrative Agent, if required), to be credited and applied against the Obligations, whether matured or unmatured, in accordance with <u>Section 6.1(b); provided</u> that if such Grantor has made payment to the Administrative Agent of all or any part of the Obligations and the Termination Date has occurred, then at such Grantor's request, the Administrative Agent will, at the expense of such Grantor, execute and deliver to such Grantor appropriate documents (without recourse and without representation or warranty) necessary to evidence the transfer by subrogation to such Grantor of an interest in the Obligations resulting from such payment. In furtherance of the foregoing, at all times prior to the Termination Date, such Grantor shall refrain from taking any action or commencing any proceeding against the Borrower, Holdings or any other Grantor (or their successors or assigns, whether in connection with a bankruptcy proceeding or otherwise) to recover any amounts in respect of payments made under this Security Agreement to the Administrative Agent or any other Secured Party.

ARTICLE III REPRESENTATIONS AND WARRANTIES

In order to induce the Secured Parties to enter into the Credit Agreement and make the Loans thereunder, the Grantors represent and warrant to the Administrative Agent, for the benefit of the Secured Parties, as set forth below.

SECTION 3.1. As to Capital Securities of the Subsidiaries, Investment Property.

- (a) With respect to any Subsidiary of any Grantor that is:
- (i) a corporation, business trust, joint stock company or similar Person, all Capital Securities issued by such Subsidiary are duly authorized and validly issued, fully paid and non-assessable, and represented by a certificate or certificates; and
- (ii) a partnership or limited liability company, no Capital Securities issued by such Subsidiary (including the Borrower) (A) is dealt in or traded on securities exchanges or in securities markets, (B) expressly provides that such Capital Securities is a security governed by Article 8 of the UCC or (C) is held in a Securities Account, except, with respect to this <u>clause (a)(ii)</u>, Capital Securities (x) for which the Administrative Agent is the registered owner or (y) with respect to which the issuer has agreed in an authenticated record with such Grantor and the Administrative Agent to comply with any instructions of the Administrative Agent without the consent of such Grantor.
- (b) Each Grantor has delivered all Certificated Securities constituting Collateral held by such Grantor in a Subsidiary (including the Borrower) on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement) to the Administrative Agent, together with duly executed undated blank stock powers, or other equivalent instruments of transfer acceptable to the Administrative Agent.

(c) [Reserved]

- (d) The percentage of the issued and outstanding Capital Securities of each Subsidiary (including the Borrower) pledged on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement) by each Grantor hereunder is as set forth on <u>Schedule I</u>. All shares of such Capital Securities have been duly and validly issued and are fully paid and non-assessable (in the case of any Capital Securities issued by a corporation) or duly issued and outstanding (in the case of any Capital Securities in any partnership or limited liability company).
- (e) Each of the Intercompany Notes constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting creditors' rights generally, general equitable principles (whether considered in a proceeding in equity or at Law) and an implied covenant of good faith and fair dealing.
- SECTION 3.2. <u>Grantor Name, Location, Etc</u>. In each case as of the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement):
- (a) (i) The jurisdiction in which each Grantor is located for purposes of Sections 9-301 and 9-307 of the UCC and (ii) the address of each Grantor's executive office and principal place of business is set forth in <u>Item A</u> of <u>Schedule II</u>.
 - (b) The Grantors do not have any trade names other than those set forth in Item C of Schedule II hereto.

- (c) During the twelve (12) months preceding the date hereof (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, preceding the date such Grantor becomes a party to this Security Agreement), no Grantor has been known by any legal name different from the one set forth on the signature page hereto, nor has such Grantor been the subject of any merger or other corporate reorganization, except as set forth in Item D of Schedule II hereto.
- (d) Each Grantor's federal taxpayer identification number (or foreign equivalent) is (and, during the twelve (12) months preceding the date hereof (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, preceding the date such Grantor becomes a party to this Security Agreement), such Grantor has not had a federal taxpayer identification number (or equivalent) different from that) set forth in Item E of Schedule II hereto.
 - (e) No Grantor is a party to any federal, state or local government contract except as set forth in <u>Item F</u> of <u>Schedule II</u> hereto.
- (f) No Grantor maintains any Deposit Accounts, Securities Accounts or Commodity Accounts with any Person, in each case, except as set forth on Item G of Schedule II.
 - (g) No Grantor is the beneficiary of any Letters of Credit in excess of \$500,000, except as set forth on Item H of Schedule II.
 - (h) No Grantor has Commercial Tort Claims in favor of such Grantor in excess of \$500,000 except as set forth on Item I of Schedule II.
- (i) The name set forth on the signature page attached hereto (or the signature page of the supplement hereto by which such Grantor has become a party to this Security Agreement, as applicable) is the true and correct legal name (as defined in the UCC) of each Grantor.
- SECTION 3.3. Ownership, No Liens, Etc. Each Grantor owns its Collateral free and clear of any Lien, except for (a) any security interest created by this Security Agreement and (b) Permitted Liens. No effective UCC financing statement or other filing similar in effect covering all or any part of the Collateral is on file in any recording office, except those filed in favor of the Administrative Agent relating to this Security Agreement, Permitted Liens or as to which a duly authorized termination statement relating to such UCC financing statement or other instrument has been delivered to the Administrative Agent on the Closing Date. No Grantor has granted a Lien (other than non-consensual Permitted Liens and Permitted Liens described in clauses (a) and (k) of Section 8.3 of the Credit Agreement) in any Bioprojet Agreement to any Person, other than the Secured Parties to the extent contemplated under this Agreement.

SECTION 3.4. Possession of Inventory, Control, Etc.

(a) Each Grantor has, and agrees that it will maintain, exclusive possession of its Documents, Instruments, Promissory Notes, Goods, Equipment and Inventory, other than (i) Equipment or Inventory that is in transit in the ordinary course of business, (ii) Equipment or Inventory that in the ordinary course of business is in the possession or control of a warehouseman,

bailee agent or other Person (other than a Person controlled by or under common control with such Grantor), with respect to any such assets with an aggregate value in excess of \$2,000,000, that has been notified of the security interest created in favor of the Administrative Agent, for the benefit of the Secured Parties, pursuant to this Security Agreement and with respect to which such Grantor has exercised commercially reasonable efforts to have authenticated a record acknowledging that such warehouseman, bailee agent or other Person holds possession of such Collateral for the benefit of the Secured Parties and waives any Lien held by it against such Collateral, (iii) Inventory that is in the possession of any Person in connection with a conditional sale, title retention, consignment or similar arrangements for sale of goods or products in the ordinary course of business and (iv) any Documents, Instruments, Promissory Notes, Goods, Equipment and Inventory that have been delivered to the Administrative Agent.

- (b) Each Grantor is the sole entitlement holder of its Deposit Accounts, and no other Person (other than the Administrative Agent pursuant to this Security Agreement or any other Person with respect to Permitted Liens) has control or possession of, or any other interest in, any of its Deposit Accounts or any other securities or property credited thereto, in each case, except as otherwise expressly permitted under the Credit Agreement.
- SECTION 3.5. <u>Negotiable Instruments and Chattel Paper</u>. Each Grantor has delivered to the Administrative Agent possession of all originals of all Instruments, Promissory Notes and tangible Chattel Paper (other than any Intercompany Note, any Instrument, Promissory Note or tangible Chattel Paper held in a Securities Account or any Instrument, Promissory Note or tangible Chattel Paper not exceeding \$500,000 in principal amount individually or \$1,000,000 in principal amount in the aggregate) held by such Grantor on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement).
- SECTION 3.6. <u>Intellectual Property Collateral</u>. Except as disclosed on <u>Schedules III</u> through <u>VI</u>, with respect to any Intellectual Property Collateral:
- (a) any material Intellectual Property Collateral owned by any Grantor is, to the knowledge of such Grantor, valid, subsisting, unexpired and enforceable and has not been abandoned or adjudged invalid or unenforceable, in whole or in part;
- (b) such Grantor is the sole and exclusive owner of the entire and unencumbered right, title and interest in and to all Intellectual Property Collateral owned by such Grantor and to the knowledge of such Grantor, no claim has been made that the use of such Intellectual Property Collateral by such Grantor does or may, conflict with, infringe, misappropriate, dilute, misuse or otherwise violate in any material respect, any of the rights of any third party;
- (c) such Grantor has made all necessary filings and recordations to protect its interest in any Intellectual Property Collateral owned by such Grantor to the extent such filing or recordation is necessary for the conduct of the business substantially in the manner presently conducted, including recordations of all of its interests in the Patent Collateral and Trademark Collateral in the USPTO or foreign equivalent, and its claims to the Copyright Collateral in the United States Copyright Office (the "<u>USCO</u>") or foreign equivalent, and, to the extent necessary, has used proper statutory notice in connection with its use of any material Patent, Trademark and Copyright in any of such Intellectual Property Collateral;

- (d) such Grantor has taken all reasonable steps to safeguard its Trade Secrets and to its knowledge (i) none of the Trade Secrets of such Grantor has been used, divulged, disclosed or appropriated for the benefit of any other Person other than a Grantor; (ii) no employee, independent contractor or agent of such Grantor has misappropriated any Trade Secrets of any other Person in the course of the performance of his or her duties as an employee, independent contractor or agent of such Grantor is in default or breach of any material term of any employment agreement, non-disclosure agreement, assignment of inventions agreement or similar agreement or contract relating in any material way to the protection, ownership, development, use or transfer of such Grantor's Intellectual Property Collateral;
- (e) to such Grantor's knowledge, no third party is infringing upon any Intellectual Property owned or used by such Grantor in any material respect, or any of its respective licensees in any material respect;
- (f) no written settlement or consents, covenants not to sue, nonassertion assurances, or releases have been entered into by such Grantor or to which such Grantor is bound that adversely affects its rights to own or use any Intellectual Property in any material respect;
- (g) such Grantor has not granted a Lien in any Intellectual Property Collateral owned by such Grantor that has not been terminated or released except Permitted Liens;
- (h) such Grantor has executed and delivered to the Administrative Agent Intellectual Property Collateral security agreements for all applications and registrations for all Copyrights, Patents and Trademarks owned by such Grantor;
- (i) such Grantor uses commercially reasonable efforts designed to ensure the quality of the manufacture, distribution and sale of all products sold by the Grantor and in the provision of all services rendered under or in connection with all Trademarks and has taken all commercially reasonable actions necessary to ensure that all licensees of the Trademarks owned by such Grantor use such adequate standards of quality;
- (j) the consummation of the transactions contemplated by the Credit Agreement and this Security Agreement will not result in the termination or material impairment of any material portion of the Intellectual Property Collateral; and
- (k) to such Grantor's knowledge, such Grantor owns or is entitled to use by license, lease or other agreement, all Patents, Trademarks, Trade Secrets, Copyrights, mask works, licenses, technology, know-how, processes and rights with respect to any of the foregoing as necessary to conduct the business and operations of such Grantor substantially in the manner presently conducted.

SECTION 3.7. Validity, Etc.

- (a) This Security Agreement creates a valid security interest in the Collateral securing the payment of the Obligations to the extent such security interest may be created pursuant to Article 9 of the UCC.
- (b) Upon the filing of a UCC-1 financing statement naming the applicable Grantor as debtor, the Administrative Agent as secured party and listing all personal property as the collateral (collectively, the "Financing Statements") in the jurisdiction of organization of each Grantor set forth in Item A of Schedule II with the appropriate agencies therefor, the security interests created under this Security Agreement shall constitute a perfected security interest in the Collateral described on such Financing Statements in favor of the Administrative Agent to the extent that a security interest therein may be perfected by filing a financing statement pursuant to the relevant UCC, prior to all other Liens, except for Permitted Liens.
- SECTION 3.8. <u>Authorization, Approval, Etc.</u> Except as have been obtained or made and are in full force and effect or except with respect to the Financing Statements or, with respect to Intellectual Property Collateral, the recordation of any agreements with the USPTO or the USCO, no authorization, approval or other action by, and no notice to or filing with, any Governmental Authority is required for the grant by the Grantors of the security interest granted hereby or for the execution, delivery and performance of this Security Agreement by the Grantors.
- SECTION 3.9. <u>Best Interests</u>. It is in the best interests of each Grantor (other than the Borrower) to execute this Security Agreement inasmuch as such Grantor will, as a result of being an Affiliate of the Borrower, derive substantial direct and indirect benefits from the Loans made to the Borrower by the Lenders pursuant to the Credit Agreement, and each Grantor agrees that the Lenders are relying on this representation in agreeing to make such Loans pursuant to the Credit Agreement to the Borrower.

ARTICLE IV COVENANTS

Each Grantor covenants and agrees that, until the Termination Date, such Grantor will perform, comply with and be bound by the obligations set forth below.

- SECTION 4.1. As to Investment Property, Etc.
- SECTION 4.1.1. Capital Securities of Subsidiaries. No Grantor will allow any of its Subsidiaries (including the Borrower):
 - (a) that is a corporation, business trust, joint stock company or similar Person, to issue Uncertificated Securities;
- (b) that is a partnership or limited liability company, to (i) issue Capital Securities that are to be dealt in or traded on securities exchanges or in securities markets, (ii) expressly provide in its Organic Documents that its Capital Securities are securities governed by Article 8 of the UCC or (iii) place such Subsidiary's Capital Securities in a Securities Account; and

(c) to issue Capital Securities in addition to or in substitution for the Capital Securities pledged hereunder, except to such Grantor (and such Capital Securities are immediately pledged and delivered to the Administrative Agent pursuant to the terms of this Security Agreement).

SECTION 4.1.2. Investment Property (other than Certificated Securities).

- (a) Upon (or such later date as Administrative Agent may agree to) a Grantor's acquisition or creation of any Deposit Accounts or Securities Accounts (other than Excluded Accounts), such Grantor will cause the bank or securities intermediary maintaining such deposit Accounts or Securities Account to execute a Control Agreement relating thereto.
- (b) With respect to any Uncertificated Securities (other than Uncertificated Securities credited to a Securities Account) issued by a Person other than the Borrower or a Subsidiary constituting Investment Property owned or held by any Grantor, such Grantor will, upon written request from Administrative Agent, cause the issuer of such securities to either (i) register the Administrative Agent as the registered owner thereof on the books and records of the issuer or (ii) execute a Control Agreement relating to such Investment Property pursuant to which the issuer agrees to comply with the Administrative Agent's instructions with respect to such Uncertificated Securities without further consent by such Grantor. With respect to Uncertificated Securities of the Borrower or any Subsidiary, the Grantor issuer of such Securities hereby agrees to comply with the Administrative Agent's instructions with respect to such Uncertificated Securities without further consent by such Grantor, and the Administrative Agent hereby agrees not to give such instructions unless an Event of Default has occurred and is continuing.
- (c) Except as otherwise permitted under the Credit Agreement (including Permitted Liens), no Grantor shall cause or permit any Person other than Administrative Agent or the Secured Parties to have "control" (as defined in Section 9-104, 9-105, 9-106 or 9-107 of the UCC) of any Investment Property constituting part of the Collateral.
- SECTION 4.1.3. <u>Certificated Securities (Stock Powers)</u>. Each Grantor agrees that all Certificated Securities constituting Collateral, including the Capital Securities delivered by such Grantor pursuant to this Security Agreement, will be accompanied by duly executed undated blank stock powers, or other equivalent instruments of transfer reasonably acceptable to the Administrative Agent.
- SECTION 4.1.4. Continuous Pledge. Each Grantor will (subject to the terms of the Credit Agreement) deliver to the Administrative Agent all Investment Property and all Payment Intangibles that constitute Collateral to the extent that such Investment Property or Payment Intangibles are evidenced by a Document, Instrument, Promissory Note or Chattel Paper (other than any Intercompany Notes, any Document, Instrument, Promissory Note or Chattel Paper held in a Securities Account or any Document, Instrument, Promissory Note or Chattel Paper not exceeding \$500,000 in principal amount individually or \$1,000,000 in principal amount in the aggregate).

SECTION 4.1.5. Voting Rights, Dividends, Etc. Each Grantor agrees:

- (a) upon receipt of notice of the occurrence and continuance of an Event of Default from the Administrative Agent and request therefor by the Administrative Agent, so long as such Event of Default shall continue, to deliver (properly endorsed where required hereby or requested by the Administrative Agent) to the Administrative Agent all dividends and Distributions with respect to Investment Property constituting Collateral; all interest, principal, other cash payments on Payment Intangibles; and all Proceeds of the Collateral, in each case thereafter received by such Grantor, all of which shall be held by the Administrative Agent as additional Collateral, except for payments made in accordance with Section 8.6 of the Credit Agreement; and
- (b) immediately upon the occurrence and during the continuance of an Event of Default and so long as the Administrative Agent has notified such Grantor of the Administrative Agent's intention to exercise its voting power under this <u>clause</u> (b),
- (i) with respect to Collateral consisting of general partner interests or limited liability company interests, to promptly modify its Organic Documents to admit the Administrative Agent as a general partner or member, as applicable;
- (ii) that the Administrative Agent may exercise (to the exclusion of such Grantor) the voting power and all other incidental rights of ownership with respect to any Investment Property constituting Collateral, and such Grantor hereby grants the Administrative Agent an irrevocable proxy, exercisable under such circumstances, to vote such Investment Property; and
- (iii) to promptly deliver to the Administrative Agent such additional proxies and other documents as are reasonably requested by Administrative Agent which are necessary to allow the Administrative Agent to exercise such voting power.

All dividends, Distributions, interest, principal, cash payments, Payment Intangibles and Proceeds constituting Collateral that may at any time and from time to time be held by such Grantor, but which such Grantor is then obligated to deliver to the Administrative Agent, shall, until delivery to the Administrative Agent, be held by such Grantor separate and apart from its other property in trust for the Administrative Agent. The Administrative Agent agrees that unless an Event of Default shall have occurred and be continuing and the Administrative Agent shall have given the notice referred to in this <u>clause (b)</u>, such Grantor will have the exclusive voting power with respect to any Investment Property and the Administrative Agent will, upon the written request of such Grantor, promptly deliver such proxies and other documents, if any, as shall be reasonably requested by such Grantor which are necessary to allow such Grantor to exercise that voting power; <u>provided</u> that no vote shall be cast, or consent, waiver or ratification given, or action taken by such Grantor that would impair any such Collateral or be inconsistent with or violate any provision of any Loan Document.

SECTION 4.2. <u>Change of Name</u>, <u>Etc</u>. No Grantor will change its name or place of incorporation or organization or federal taxpayer identification number except as otherwise permitted by the Credit Agreement.

SECTION 4.3. As to Accounts.

- (a) Each Grantor shall have the right to collect all Accounts so long as no Event of Default shall have occurred and be continuing.
- (b) Upon (i) the occurrence and continuance of an Event of Default and (ii) the delivery of notice by the Administrative Agent to each Grantor, all Proceeds of Collateral received by such Grantor shall be delivered in kind to the Administrative Agent and, until delivered to Administrative Agent, shall be deposited in a Deposit Account of such Grantor maintained with the Administrative Agent or that otherwise is a Controlled Account (such Deposit Accounts or Controlled Accounts, collectively, the "Collateral Accounts"), and such Grantor shall not commingle any such Proceeds and shall hold, separate and apart from all other property, all such Proceeds in express trust for the benefit of the Administrative Agent until delivery thereof is made to the Administrative Agent.
- (c) Following the delivery of notice pursuant to <u>clause (b)(ii)</u> above, the Administrative Agent shall have the right to apply any amount in the Collateral Accounts to the payment of any Obligations which are then due and payable in accordance with Section 9.4 of the Credit Agreement.

SECTION 4.4. As to Grantors' Use of Collateral.

- (a) Subject to <u>clause (b)</u> below, each Grantor: (i) may in the ordinary course of its business, at its own expense, sell, lease or furnish under contracts of service any of the Inventory normally held by such Grantor for such purpose, and use and consume, in the ordinary course of its business, any raw materials, work in process or materials normally held by such Grantor for such purpose, (ii) will, at its own expense, endeavor to collect, as and when due, all amounts due with respect to any of the Collateral, including the taking of such action with respect to such collection as the Administrative Agent may reasonably request following the occurrence and during the continuance of an Event of Default or, in the absence of such request, as such Grantor may deem advisable, (iii) may grant, in the ordinary course of business, to any party obligated on any of the Collateral, any rebate, refund or allowance to which such party may be lawfully entitled, and may accept, in connection therewith, the return of Goods, the sale or lease of which shall have given rise to such Collateral, or (iv) may make Dispositions permitted under the Credit Agreement.
- (b) At any time following the occurrence and during the continuance of an Event of Default, whether before or after the maturity of any of the Obligations until the Termination Date, the Administrative Agent may: (i) revoke any or all of the rights of each Grantor set forth in <u>clause</u> (a) above, (ii) notify any parties obligated on any of the Collateral to make payment to the Administrative Agent of any amounts due or to become due thereunder and (iii) enforce collection of any of the Collateral by suit or otherwise and surrender, release or exchange all or any part thereof, or compromise or extend or renew for any period (whether or not longer than the original period) any indebtedness thereunder or evidenced thereby.
- (c) Upon the request of the Administrative Agent following the occurrence and during the continuance of an Event of Default, each Grantor will, at its own expense, notify any parties obligated on any of the Collateral to make payment to the Administrative Agent of any amounts due or to become due thereunder.

- (d) At any time following the occurrence and during the continuance of an Event of Default, the Administrative Agent may endorse, in the name of such Grantor, any item, howsoever received by the Administrative Agent, representing any payment on or other Proceeds of any of the Collateral.
- (e) No Grantor may grant a Lien (other than non-consensual Permitted Liens and Permitted Liens described in clauses (a) and (k) of Section 8.3 of the Credit Agreement) on any Bioprojet Agreement to any Person, other than the Secured Parties.
- SECTION 4.5. <u>As to Intellectual Property Collateral</u>. Each Grantor covenants and agrees to comply with the following provisions as such provisions relate to any Intellectual Property Collateral material to the operations or business of such Grantor:
- (a) such Grantor will not (i) do or fail to perform any act whereby any of the Patent Collateral may lapse or become abandoned or dedicated to the public or unenforceable, (ii) authorize any of its licensees to (A) fail to continue to use any of the Trademark Collateral in order to maintain all of the Trademark Collateral in full force free from any claim of abandonment for non-use, (B) fail to maintain the quality of products and services offered under all of the Trademark Collateral at a level substantially consistent with the quality of products and services offered under such Trademark as of the date hereof, (C) [reserved], (D) [reserved], (E) [reserved] or (F) do or permit any act or knowingly omit to do any act whereby any of the Trademark Collateral may become invalid or unenforceable or (iii) do or permit any act or knowingly omit to do any act whereby any of the Copyright Collateral or any of the Trade Secrets Collateral may lapse or become invalid or unenforceable or placed in the public domain except upon expiration of the end of an unrenewable term of a registration thereof, unless, in the case of any of the foregoing requirements in clauses (i), (ii) and (iii), such Grantor reasonably and in good faith determines that either (x) such Intellectual Property Collateral is of negligible economic value to such Grantor or (y) the loss of such Intellectual Property Collateral would not be material to such Grantor;
- (b) such Grantor shall promptly notify the Administrative Agent if it knows that any application or registration relating to any material item of the Intellectual Property Collateral may, in the Grantor's reasonable commercial judgment, become abandoned or dedicated to the public or placed in the public domain or invalid or unenforceable, or of any adverse determination (including the institution of, or any such determination in, any proceeding in the USPTO, the USCO or any foreign counterpart thereof or any court) regarding such Grantor's ownership of any of the Intellectual Property Collateral, its right to register the same or to keep and maintain and enforce the same;
- (c) deliver, on a quarterly basis, together with the delivery of the applicable Compliance Certificate for such quarter, a report listing all applications for the registration of any Intellectual Property Collateral with the USPTO or any similar office or agency in any other country or any political subdivision thereof filed during such quarter, and upon the request of the Administrative Agent (subject to the terms of the Credit Agreement and this Security Agreement), the applicable Grantor shall execute and deliver all agreements, instruments and documents as the Administrative Agent may reasonably request to evidence the Administrative Agent's security interest in any Intellectual Property Collateral;

(d) [reserved]

- (e) such Grantor will take all reasonable and necessary steps (in such Grantor's reasonable business judgement), including in any proceeding before the USPTO, the USCO or any similar office or agency in any other country or any political subdivision thereof (subject to the terms of the Credit Agreement), to maintain and pursue any material application (and to obtain the relevant registration) filed with respect to, and to maintain any registration of, material Intellectual Property Collateral, including the filing of applications for renewal, affidavits of use, affidavits of incontestability and opposition, interference and cancellation proceedings and the payment of fees and taxes (except to the extent that dedication, abandonment or invalidation is permitted under the foregoing clause (a) or (b)); and
- (f) such Grantor will promptly (but no less than quarterly and sooner if requested by Administrative Agent) execute and deliver to the Administrative Agent (as applicable) a Patent Security Agreement, Trademark Security Agreement and/or Copyright Security Agreement, as the case may be, in the forms of Exhibit A, Exhibit B and Exhibit C hereto following its obtaining an interest in any such Intellectual Property and shall execute and deliver to the Administrative Agent any other document reasonably required to evidence the Administrative Agent's interest in any part of such item of Intellectual Property Collateral unless such Grantor shall determine in good faith (with the consent of the Administrative Agent, such consent not to be unreasonably withheld) that any Intellectual Property Collateral is of negligible economic value to such Grantor.

SECTION 4.6. As to Letter of Credit Rights.

- (a) Each Grantor, by granting a security interest in its Letter of Credit Rights to the Administrative Agent, intends to (and hereby does) collaterally assign to the Administrative Agent its rights (including its contingent rights) to the Proceeds of all Letter of Credit Rights of which it is or hereafter becomes a beneficiary or assignee.
- (b) Upon the occurrence of an Event of Default, such Grantor will, promptly upon request by the Administrative Agent, (i) notify (and such Grantor hereby authorizes the Administrative Agent to notify) the issuer and each nominated person with respect to each of the Letters of Credit that the Proceeds thereof have been assigned to the Administrative Agent hereunder and any payments due or to become due in respect thereof are to be made directly to the Administrative Agent and (ii) arrange for the Administrative Agent to become the transferee beneficiary of such Letter of Credit.
- SECTION 4.7. <u>As to Commercial Tort Claims</u>. Each Grantor covenants and agrees that, until the Termination Date, with respect to any Commercial Tort Claim exceeding \$500,000 hereafter arising, it shall deliver to the Administrative Agent a reasonably detailed description of any such new Commercial Tort Claim.
- SECTION 4.8. <u>Electronic Chattel Paper and Transferable Records</u>. If any Grantor at any time holds or acquires an interest in any Electronic Chattel Paper or any "transferable record," as that term is defined in Section 201 of the U.S. Federal Electronic Signatures in Global and National Commerce Act or in Section 16 of the U.S. Uniform Electronic Transactions Act, as in effect in

any relevant jurisdiction, with a value in excess of \$500,000, such Grantor shall promptly notify the Administrative Agent thereof and, at the request of the Administrative Agent, shall take such action as the Administrative Agent may reasonably request to vest in the Administrative Agent control under Section 9-105 of the UCC of such Electronic Chattel Paper or control under Section 201 of the Federal Electronic Signatures in Global and National Commerce Act or, as the case may be, Section 16 of the Uniform Electronic Transactions Act, as so in effect in such jurisdiction, of such transferable record. The Administrative Agent agrees with such Grantor that the Administrative Agent will arrange, pursuant to procedures reasonably satisfactory to the Administrative Agent and so long as such procedures will not result in the Administrative Agent's loss of control, for the Grantor to make alterations to the Electronic Chattel Paper or transferable record permitted under Section 9-105 of the UCC or, as the case may be, Section 201 of the U.S. Federal Electronic Signatures in Global and National Commerce Act or Section 16 of the U.S. Uniform Electronic Transactions Act for a party in control to allow without loss of control, unless an Event of Default has occurred and is continuing or would occur after taking into account any action by such Grantor with respect to such Electronic Chattel Paper or transferable record.

SECTION 4.9. <u>Further Assurances, Etc.</u> Each Grantor agrees that, from time to time at its own expense, it will, subject to the terms of this Security Agreement, promptly execute and deliver all further instruments and documents, and take all further action, that may be necessary or that the Administrative Agent may reasonably request, in order to perfect, preserve and protect any security interest granted hereby or to enable the Administrative Agent to exercise and enforce its rights and remedies hereunder with respect to any Collateral. Without limiting the generality of the foregoing, such Grantor will:

(a) from time to time upon the written request of the Administrative Agent, promptly deliver to the Administrative Agent such stock powers, instruments and similar documents, reasonably satisfactory in form and substance to the Administrative Agent, with respect to Capital Securities constituting Collateral as are necessary to perfect the security interest created hereunder and will, from time to time upon the prior written request of the Administrative Agent, after the occurrence and during the continuance of any Event of Default, promptly transfer any Capital Securities constituting Collateral into the name of any nominee designated by the Administrative Agent; if any Collateral shall be evidenced by an Instrument, negotiable Document, Promissory Note or tangible Chattel Paper, deliver and pledge to the Administrative Agent hereunder such Instrument, negotiable Document, Promissory Note or tangible Chattel Paper (other than any Intercompany Note, any Instrument, negotiable Document, Promissory Note or tangible Chattel Paper held in a Securities Account subject to a Control Agreement or any Instrument, negotiable Document, Promissory Note or tangible Chattel Paper not exceeding \$500,000 in principal amount individually) duly endorsed and accompanied by duly executed instruments of transfer or assignment, all in form and substance reasonably satisfactory to the Administrative Agent;

(b) file (and hereby authorize the Administrative Agent to file) such Financing Statements or continuation statements, or amendments thereto, and such other instruments or notices (including any assignment of claim form under or pursuant to the federal assignment of claims statute, 31 U.S.C. § 3727, any successor or amended version thereof or any regulation promulgated under or pursuant to any version thereof), as may be necessary or that the Administrative Agent may reasonably request in order to perfect and preserve the security interests and other rights granted or purported to be granted to the Administrative Agent, for the benefit of the Secured Parties, hereby;

(c) [reserved];

- (d) not take or omit to take any action the taking or the omission of which would result in any impairment or alteration of any obligation of the maker of any Payment Intangible or other Instrument constituting Collateral, except as provided in <u>Section 4.4</u>; and
- (e) not create any tangible Chattel Paper with a value in excess of \$500,000 individually or \$1,000,000 in the aggregate, without placing a legend on such tangible Chattel Paper reasonably acceptable to the Administrative Agent indicating that the Administrative Agent has a security interest in such Chattel Paper.

With respect to the foregoing and the grant of the security interest hereunder, each Grantor hereby authorizes the Administrative Agent to file one or more financing or continuation statements, and amendments thereto, relative to all or any part of the Collateral as may be necessary or desirable to create, preserve, perfect or maintain the perfection of or validate the security interest granted hereunder. Each Grantor agrees that a carbon, photographic or other reproduction of this Security Agreement or any UCC financing statement covering the Collateral or any part thereof shall be sufficient as a UCC financing statement where permitted by Law. Each Grantor hereby authorizes the Administrative Agent to file financing statements describing as the collateral covered thereby "all of the debtor's personal property or assets" or words to that effect, notwithstanding that such wording may be broader in scope than the Collateral described in this Security Agreement.

ARTICLE V THE ADMINISTRATIVE AGENT

- SECTION 5.1. <u>Agent Appointed Attorney-in-Fact</u>. Each Grantor hereby designates and appoints the Administrative Agent, on behalf of the Secured Parties, and each of its designees or agents, as attorney-in-fact of such Grantor, irrevocably and with power of substitution, with authority to take any or all of the following actions upon the occurrence and during the continuance of an Event of Default until the Termination Date in accordance with the terms hereof:
- (a) to demand, collect, settle, compromise and adjust, and give discharges and releases concerning the Collateral, all as the Administrative Agent may deem reasonably appropriate;
- (b) to commence and prosecute any actions at any court for the purposes of collecting any of the Collateral and enforcing any other right in respect thereof;
- (c) to defend, settle or compromise any action brought in respect of the Collateral and, in connection therewith, give such discharge or release as the Administrative Agent may deem reasonably appropriate;

- (d) to pay or discharge taxes, liens, security interests or other encumbrances levied or placed on or threatened against the Collateral;
- (e) to direct any parties liable for any payment in connection with any of the Collateral to make payment of any and all monies due and to become due thereunder directly to the Administrative Agent or as the Administrative Agent shall direct;
- (f) to receive payment of and receipt for any and all monies, claims, and other amounts due and to become due at any time in respect of or arising out of any Collateral;
 - (g) to sign and endorse any drafts, assignments, proxies, stock powers, verifications, notices and other documents relating to the Collateral;
- (h) to execute and deliver all assignments, conveyances, statements, financing statements, renewal financing statements, security and pledge agreements, affidavits, notices and other agreements, instruments and documents that the Administrative Agent may deem reasonably appropriate in order to perfect and maintain the security interests and liens granted in this Agreement and in order to fully consummate all of the transactions contemplated therein;
- (i) to exchange any of the Collateral or other property upon any merger, consolidation, reorganization, recapitalization or other readjustment of the issuer thereof and, in connection therewith, deposit any of the Collateral with any committee, depository, transfer agent, registrar or other designated agency upon such terms as the Administrative Agent may deem reasonably appropriate;
- (j) to vote for a shareholder or member resolution, or to sign an instrument in writing, sanctioning the transfer of any or all of the Collateral into the name of the Administrative Agent or one or more of the Secured Parties or into the name of any transferee to whom the Collateral or any part thereof may be sold pursuant to Article VI hereof; and
 - (k) to perform the affirmative obligations of such Grantor hereunder.

This power of attorney is a power coupled with an interest and shall be irrevocable for so long as any of the Obligations (other than contingent indemnification obligations for which no claim has been asserted) shall remain outstanding and until all of the commitments relating thereto shall have been terminated. The Administrative Agent shall be under no duty to exercise or withhold the exercise of any of the rights, powers, privileges and options expressly or implicitly granted to the Administrative Agent in this Agreement, and shall not be liable for any failure to do so or any delay in doing so. The Administrative Agent shall not be liable for any act or omission or for any error of judgment or any mistake of fact or law in its individual capacity or its capacity as attorney-in-fact except acts or omissions resulting from its gross negligence or willful misconduct. This power of attorney is conferred on the Administrative Agent solely to protect, preserve and realize upon its security interest in the Collateral.

SECTION 5.2. <u>Assignment by the Administrative Agent</u>. The Administrative Agent may from time to time assign its security interest in the Collateral to a successor agent in accordance with the Credit Agreement, and the assignee shall be entitled to all of the rights and remedies of the Administrative Agent under this Agreement in relation thereto.

SECTION 5.3. The Administrative Agent hereunder and to account for all proceeds thereof, the Administrative Agent shall have no duty or liability to preserve rights pertaining thereto, it being understood and agreed that the Grantors shall be responsible for preservation of all rights in the Collateral, and the Administrative Agent shall be relieved of all responsibility for the Collateral upon surrendering it or tendering the surrender of it to the Grantors. The Administrative Agent shall be deemed to have exercised reasonable care in the custody and preservation of the Collateral in its possession if such Collateral is accorded treatment substantially equal to that which the Administrative Agent accords its own property, which shall be no less than the treatment employed by a reasonable and prudent agent in the industry, it being understood that the Administrative Agent shall not have responsibility for (i) ascertaining or taking action with respect to calls, conversions, exchanges, maturities, tenders or other matters relating to any Collateral, whether or not the Administrative Agent has or is deemed to have knowledge of such matters or (ii) taking any necessary steps to preserve rights against any parties with respect to any of the Collateral. The provisions of Article XI of the Credit Agreement, including the rights, privileges, protections, benefits, indemnities and immunities of the Administrative Agent are incorporated herein, mutatis mutandis, as if a part hereof, and shall also apply to the Administrative Agent acting under or in connection with this Agreement.

SECTION 5.4. <u>Release of Collateral</u>. The Administrative Agent, upon the direction of the Required Lenders, may release any of the Collateral from this Security Agreement or may substitute any of the Collateral for other Collateral without altering, varying or diminishing in any way the force, effect, lien, pledge or security interest of this Agreement as to any Collateral not expressly released or substituted, and this Agreement shall continue as a first priority (subject to Permitted Liens) lien on all Collateral not expressly released or substituted.

SECTION 5.5. <u>Application of Proceeds</u>. Upon the occurrence and during the continuation of an Event of Default, any payments in respect of the Obligations and any proceeds of the Collateral, when received by the Administrative Agent or any of the Secured Parties in cash or its equivalent, will be applied in reduction of the Obligations in the order set forth in Section 9.4 of the Credit Agreement, and each Grantor irrevocably waives the right to direct the application of such payments and proceeds and acknowledges and agrees that the Administrative Agent shall have the continuing and exclusive right to apply and reapply any and all such payments and proceeds in accordance with Section 9.4 of the Credit Agreement.

ARTICLE VI REMEDIES

SECTION 6.1. Certain Remedies. If any Event of Default shall have occurred and be continuing:

(a) The Administrative Agent may exercise in respect of the Collateral, in addition to other rights and remedies provided for herein or otherwise available to it, all the rights

and remedies of the Administrative Agent on default under the UCC (whether or not the UCC is in effect in the jurisdiction where the rights and remedies are asserted) and also may:

- (i) take possession of any Collateral not already in its possession without demand and without legal process;
- (ii) require each Grantor to, and each Grantor hereby agrees that it will, at its expense and upon request of the Administrative Agent forthwith, assemble all or part of the Collateral as reasonably directed by the Administrative Agent and make it available to the Administrative Agent at a place to be designated by the Administrative Agent that is reasonably convenient to both the Administrative Agent and such Grantor;
- (iii) enter onto the property where any Collateral is located and take possession thereof without demand and without legal process; and
- (iv) without notice except as specified below, lease, license, sell or otherwise dispose of the Collateral or any part thereof in one or more parcels at any public or private sale, at any of the Administrative Agent's offices or elsewhere, for cash, on credit or for future delivery, and upon such other terms as the Administrative Agent may deem commercially reasonable. Each Grantor agrees that, to the extent notice of sale shall be required by Law, at least ten (10) days' prior notice to such Grantor of the time and place of any public sale or the time after which any private sale is to be made shall constitute reasonable notification. The Administrative Agent shall not be obligated to make any sale of Collateral regardless of notice of sale having been given. The Administrative Agent may adjourn any public or private sale from time to time by announcement at the time and place fixed therefor, and such sale may, without further notice, be made at the time and place to which it was so adjourned.
- (b) All cash Proceeds received by the Administrative Agent in respect of any sale of, collection from, or other realization upon, all or any part of the Collateral shall be applied by the Administrative Agent against all or any part of the Obligations as set forth in Section 9.4 of the Credit Agreement.
 - (c) The Administrative Agent may:
- (i) transfer all or any part of the Collateral into the name of the Administrative Agent or its nominee, with or without disclosing that such Collateral is subject to the Lien hereunder;
- (ii) notify the parties obligated on any of the Collateral to make payment to the Administrative Agent of any amount due or to become due thereunder;
 - (iii) withdraw, or cause or direct the withdrawal, of all funds with respect to any Collateral Account;
- (iv) enforce collection of any of the Collateral by suit or otherwise, and surrender, release or exchange all or any part thereof, or compromise or extend or renew for any period (whether or not longer than the original period) any obligations of any nature of any party with respect thereto:

- (v) endorse any checks, drafts, or other writings in any Grantor's name to allow collection of the Collateral;
- (vi) take control of any Proceeds of the Collateral; and
- (vii) execute (in the name, place and stead of any Grantor) endorsements, assignments, stock powers and other instruments of conveyance or transfer with respect to all or any of the Collateral.
- SECTION 6.2. <u>Securities Laws</u>. If the Administrative Agent shall determine to exercise its right to sell all or any of the Collateral that are Capital Securities pursuant to <u>Section 6.1(a)(iv)</u>, each Grantor agrees that, upon written request of the Administrative Agent, such Grantor will, at its own expense:
- (a) execute and deliver, and cause (or, with respect to any issuer which is not a Subsidiary of such Grantor, use its best efforts to cause) each issuer of the Collateral contemplated to be sold and the directors and officers thereof to execute and deliver, all such instruments and documents, and do or cause to be done all such other acts and things, as may be necessary or, in the opinion of the Administrative Agent, advisable to register such Collateral under the provisions of the Securities Act of 1933, as from time to time amended and the rules and regulations of the SEC thereunder (the "Securities Act"), and cause the registration statement relating thereto to become effective and to remain effective for such period as prospectuses are required by Law to be furnished, and to make all amendments and supplements thereto and to the related prospectus which, in the opinion of the Administrative Agent, are necessary or advisable, all in conformity with the requirements of the Securities Act and the rules and regulations of the SEC applicable thereto;
- (b) use its best efforts to exempt the Collateral under the state securities or "Blue Sky" laws and to obtain all necessary governmental approvals for the sale of the Collateral, as requested by the Administrative Agent;
- (c) cause (or, with respect to any issuer that is not a Subsidiary of such Grantor, use its best efforts to cause) each such issuer to make available to its security holders, as soon as practicable, an earnings statement that will satisfy the provisions of Section 11(a) of the Securities Act; and
- (d) do or cause to be done all such other acts and things as may be necessary to make such sale of the Collateral or any part thereof valid and binding and in compliance with applicable Law.
- SECTION 6.3. <u>Compliance with Restrictions</u>. Each Grantor agrees that in any sale of any of the Collateral whenever an Event of Default shall have occurred and be continuing, the Administrative Agent is hereby authorized to comply with any limitation or restriction in connection with such sale as it may be advised by counsel is necessary in order to avoid any violation of applicable Law (including compliance with such procedures as may restrict the number of prospective bidders and purchasers, require that such prospective bidders and

purchasers have certain qualifications, and restrict such prospective bidders and purchasers to Persons who will represent and agree that they are purchasing for their own account for investment and not with a view to the distribution or resale of such Collateral), or in order to obtain any required approval of the sale or of the purchaser by any Governmental Authority or official, and such Grantor further agrees that such compliance shall not result in such sale being considered or deemed not to have been made in a commercially reasonable manner, nor shall the Administrative Agent be liable nor accountable to such Grantor for any discount allowed by the reason of the fact that such Collateral is sold in compliance with any such limitation or restriction.

SECTION 6.4. <u>Protection of Collateral</u>. The Administrative Agent may from time to time, at its option, upon the occurrence and continuance of an Event of Default, perform and take any action which the Administrative Agent deems reasonably necessary for the maintenance, preservation or protection of any of the Collateral or of its security interest therein.

ARTICLE VII MISCELLANEOUS PROVISIONS

SECTION 7.1. <u>Loan Document</u>. This Security Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.

SECTION 7.2. <u>Binding on Successors, Transferees and Assigns; Assignment</u>. This Security Agreement shall remain in full force and effect until the Termination Date has occurred, shall be binding upon the Grantors and their successors, permitted transferees and permitted assigns and shall inure to the benefit of and be enforceable by the Administrative Agent and the Secured Parties; <u>provided</u> that no Grantor may assign or transfer any of its rights or obligations hereunder without the prior consent of the Administrative Agent.

SECTION 7.3. <u>Amendments, Etc.</u> No amendment or modification to or waiver of any provision of this Security Agreement, nor consent to any departure by any Grantor from its obligations under this Security Agreement, shall in any event be effective unless the same shall be in writing and signed by the Administrative Agent and the Grantors and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

SECTION 7.4. <u>Notices</u>. All notices and other communications provided for hereunder shall be delivered or made as provided in Section 10.2 of the Credit Agreement.

SECTION 7.5. Release of Liens. Upon (a) the Disposition of Collateral to a Person that is not a Grantor or a Subsidiary of a Grantor in accordance with the Credit Agreement and (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Collateral (in the case of clause (a)) or (ii) all Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantors' sole expense, deliver to the Grantors, without any representations, warranties or recourse of any kind whatsoever, all Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantors such documents as the Grantors shall reasonably request to evidence such termination. Upon the occurrence of the Termination Date, this Security Agreement shall automatically terminate.

SECTION 7.6. <u>Additional Grantors</u>. Upon the execution and delivery by any other Person of a supplement in the form of <u>Annex I</u> hereto, such Person shall become a "Grantor" hereunder with the same force and effect as if it were originally a party to this Security Agreement and named as a "Grantor" hereunder. The execution and delivery of such supplement shall not require the consent of any other Grantor hereunder, and the rights and obligations of each Grantor hereunder shall remain in full force and effect notwithstanding the addition of any new Grantor as a party to this Security Agreement. Any schedules delivered by any additional Grantor pursuant to such supplement shall supplement the relevant schedules to this Security Agreement.

SECTION 7.7. No Waiver; Remedies. In addition to, and not in limitation of Section 2.5, no failure on the part of the Administrative Agent to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right hereunder preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by Law.

SECTION 7.8. <u>Severability</u>. Any provision of this Security Agreement which is prohibited or unenforceable in any jurisdiction shall, as to such provision and such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of this Security Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

SECTION 7.9. Governing Law, Entire Agreement, Etc. THIS SECURITY AGREEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR ANY DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Security Agreement, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter thereof and supersedes any prior agreements, written or oral, with respect thereto.

SECTION 7.10. <u>Counterparts</u>. This Security Agreement may be executed by the parties hereto in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. This Security Agreement shall become effective when counterparts hereof executed on behalf of all of the signatories hereto, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Security Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Security Agreement.

SECTION 7.11. <u>Rights of Required Lenders</u>. If the Administrative Agent has resigned and no successor agent has been appointed pursuant to Section 10.10 of the Credit Agreement, all rights of the Administrative Agent hereunder may be exercised by the Required Lenders.

IN WITNESS WHEREOF, each of the parties hereto has caused this Security Agreement to be duly executed and delivered by its Authorized Officer as of the date first above written.

Ву:	Name: Title:
НАБ	RMONY BIOSCIENCES II, INC.
By:	Name: Title:
III, I	SIMED ROYALTY & CREDIT OPPORTUNITIES LP e Administrative Agent
Ву:	OrbiMed ROF III LLC, its General Partner
Ву:	OrbiMed Advisors LLC, its Managing Partner
By:	Name: Title: Member

HARMONY BIOSCIENCES, LLC

[Signature Page to Security Agreement]

SCHEDULE I to Security Agreement

Name of Grantor: <u>Interest:</u>

SCHEDULE II to Security Agreement

Item A. <u>Location of each Grantor</u>.

Name of Grantor: Location for purposes of UCC:

Item B. <u>Filing locations last five years</u>.

Item C. <u>Trade names</u>.

Name of Grantor: Trade Names:

Item D. <u>Merger or other corporate reorganization</u>.

Item E. <u>Grantor's federal taxpayer ID numbers</u>.

Name of Grantor: <u>Taxpayer ID numbers:</u>

 Item G.
 Deposit Accounts, Securities Accounts and Commodity Accounts.

 Name of Grantor:
 Description of Deposit Accounts, Securities Accounts and Commodity Accounts:

 Item H.
 Letter of Credit Rights.

 Item I.
 Commercial Tort Claims.

 Item J.
 Pledged Notes.

Description of Pledged Notes:

Item F.

Government Contracts.

Name of Grantor:

Item A. <u>Patents</u>.

Item B. <u>Patent Licenses</u>.

Item A. <u>Trademarks</u>.

Item B. <u>Trademark Licenses</u>.

Item A. <u>Copyrights/Mask Works</u>.

Item B. <u>Copyright/Mask Work Licenses</u>.

SCHEDULE VI to Security Agreement

Trade Secret or Know-How Licenses

PATENT SECURITY AGREEMENT

This PATENT SECURITY AGREEMENT, dated as of , 20 (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, for the benefit of the Secured Parties, dated as of January 9, 2020 (as amended, supplemented or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Patent Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.

SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Grantor's right, title and interest in and to the Patent Collateral, including each Patent and Patent application referred to in <u>Item A</u> of <u>Schedule I</u> attached hereto and each Patent license referred to in <u>Item B</u> of <u>Schedule I</u> attached hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).

SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the Patent Collateral with the USPTO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.

SECTION 4. Release of Liens. Upon (a) the Disposition of Patent Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Patent Collateral (in the case of clause (a)) or (ii) all Patent Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Patent Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.

SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Patent Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.

SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.

SECTION 7. <u>Effectiveness</u>. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF,	the Grantor hereto has caused this	Agreement to be duly	executed and delivered by i	ts Authorized Of	ficer as of the
date first above written.					

[NAME OF GRANTOR]

By:

Name: Title:

[Signature Page to Patent Security Agreement]

SCHEDULE I to Patent Security Agreement

Item A. Patents.

 Country
 Patent No.
 Issue Date
 Inventor(s)
 Title

CountrySerial No.Pending Patent ApplicationsInventor(s)Title

Item B. Patent Licenses (excluding any licenses to the Grantor for commercially available off- the-shelf software)

Country or
TerritoryLicensorEffective
LicenseeExpiration
DateSubject
Matter

TRADEMARK SECURITY AGREEMENT

This TRADEMARK SECURITY AGREEMENT, dated as of , 20 (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, dated as of January 9, 2020 (as amended, supplemented, or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Trademark Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.

SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of Grantor's right, title and interest in and to the Trademark Collateral, including those Trademarks referred to in <u>Item B</u> of <u>Schedule I</u> hereto and each Trademark license referred to in <u>Item B</u> of <u>Schedule I</u> hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).

SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the

Trademark Collateral with the USPTO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.

SECTION 4. <u>Release of Liens</u>. Upon (a) the Disposition of Trademark Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Trademark Collateral (in the case of <u>clause (a)</u>) or (ii) all Trademark Collateral (in the case of <u>clause (b)</u>). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Trademark Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.

SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Trademark Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.

SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.

SECTION 7. Effectiveness. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN WITNESS	WHEREOF, the Grantor here	eto has caused this Agr	reement to be duly	executed and delivered	d by Authorized	Officer as of the date
first above written.						

[N]	AME OF GRANTOR]
Ву	<i>y</i> :
	Name:
	Title:
[Signature Page to Trademark Security Agr	eement]

SCHEDULE I to Trademark Security Agreement

Item A. <u>Trademarks</u>.

Registered Trademarks

<u>Country</u> <u>Trademark</u> <u>Registration No.</u> <u>Registration Date</u>

Pending Trademark Applications

Country Trademark Serial No. Filing Date

Item B. <u>Trademark Licenses</u>.

 Country or
 Effective
 Expiration

 Territory
 Trademark
 Licensor
 Licensee
 Date
 Date

COPYRIGHT SECURITY AGREEMENT

This COPYRIGHT SECURITY AGREEMENT, dated as of , 20 (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, dated as of January 9, 2020 (as amended, supplemented or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Copyright Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.

SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Grantor's right, title and interest in and to the Copyright Collateral, including the Copyrights referred to in <u>Item B</u> of <u>Schedule I</u> hereto and the exclusive Copyright licenses referred to in <u>Item B</u> of <u>Schedule I</u> hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).

SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the

Copyright Collateral with the USCO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.

SECTION 4. Release of Liens. Upon (a) the Disposition of Copyright Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Copyright Collateral (in the case of clause (a)) or (ii) all Copyright Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Copyright Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.

SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Copyright Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.

SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.

SECTION 7. <u>Effectiveness</u>. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF,	the Grantor hereto has caused this	Agreement to be duly	executed and delivered by i	ts Authorized Of	ficer as of the
date first above written.					

[NAME OF GRANTOR]
Ву:
Name:
Title:
[Signature Page to Copyright Security Agreement]

SCHEDULE I to Copyright Security Agreement

Title

Copyrights/Mask Works. Item A.

> Registered Copyrights/Mask Works Country

Registration No. Registration Date Author(s)

Copyright/Mask Work Pending Registration Applications ial No. Filing Date Serial No. Country Author(s) Title

Item B. Exclusive Copyright/Mask Work Licenses.

> Effective Country or Territory Expiration Date Licensee Date Licensor

SUPPLEMENT TO PLEDGE AND SECURITY AGREEMENT

This SUPPLEMENT, dated as of [●], 20 (this "<u>Supplement</u>"), is to the Pledge and Security Agreement, dated as of January 9, 2020 (as amended, supplemented, amended and restated or otherwise modified from time to time, the "<u>Security Agreement</u>"), among the Grantors (such term, and other terms used in this Supplement, to have the meanings set forth in Article I of the Security Agreement, unless otherwise defined herein or if the context otherwise requires) from time to time party thereto, in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties (as defined below).

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, pursuant to the provisions of Section 7.6 of the Security Agreement, each of the undersigned is becoming a Grantor under the Security Agreement; and

WHEREAS, each of the undersigned desires to become a "Grantor" under the Security Agreement in order to induce the Lenders to continue to extend Loans under the Credit Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the undersigned agrees, for the benefit of the Secured Parties, as follows.

SECTION 1. Party to Security Agreement, Etc. In accordance with the terms of the Security Agreement, by its signature below, each of the undersigned hereby irrevocably agrees to become a Grantor under the Security Agreement with the same force and effect as if it were an original signatory thereto and each of the undersigned hereby (a) agrees to be bound by and comply with all of the terms and provisions of the Security Agreement applicable to it as a Grantor and (b) represents and warrants that the representations and warranties made by it as a Grantor thereunder are true and correct as of the date hereof, unless stated to relate solely to an earlier date, in which case such representations and warranties shall be true and correct as of such earlier date. In furtherance of the foregoing, each reference to a "Grantor" or "Grantors" in the Security Agreement shall be deemed to include each of the undersigned.

SECTION 2. <u>Schedules</u>. Each of the undersigned hereby authorizes the Administrative Agent to add the information set forth on the Schedules to this Supplement to the correlative Schedules attached to the Security Agreement.

SECTION 3. <u>Representations</u>. Each of the undersigned hereby represents and warrants that this Supplement has been duly authorized, executed and delivered by it and that this Supplement and the Security Agreement constitute its legal, valid and binding obligation, enforceable against it in accordance with its terms.

SECTION 4. <u>Full Force of Security Agreement</u>. Except as expressly supplemented hereby, the Security Agreement shall remain in full force and effect in accordance with its terms.

SECTION 5. Severability. Wherever possible each provision of this Supplement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Supplement shall be prohibited by or invalid under such Law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Supplement or the Security Agreement.

SECTION 6. Governing Law, Entire Agreement, Etc. THIS SUPPLEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR ANY DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Supplement, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter thereof and supersedes any prior agreements, written or oral, with respect thereto.

SECTION 7. <u>Effectiveness</u>. This Supplement shall become effective with respect to a Grantor when a counterpart hereof executed by such undersigned Grantor shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Supplement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Supplement.

[Signature Page Follows]

date first above written.	
	[NAME OF ADDITIONAL SUBSIDIARY]
	By: Name: Title:
	[NAME OF ADDITIONAL SUBSIDIARY]
	By:

IN WITNESS WHEREOF, each of the parties hereto has caused this Supplement to be duly executed and delivered by its Authorized Officer as of

[Signature Page to Security Agreement Supplement]

Name: Title: [COPY SCHEDULES FROM SECURITY AGREEMENT]

$\frac{\text{EXHIBIT F}}{\text{FORM OF ASSIGNMENT AND ASSUMPTION}}$

This Assignment and Assumption (the "Assignment and Assumption") is dated as of the Effective Date set forth below and is entered into by and between [the][each]¹ Assignor identified in item 1 below ([the][each, an] "Assignor") and [the][each]² Assignee identified in item 2 below ([the][each, an] "Assignee"). [It is understood and agreed that the rights and obligations of [the Assignors][the Assignees]³ hereunder are several and not joint.]⁴ Capitalized terms used but not defined herein shall have the meanings given to them in the Credit Agreement identified below (as amended, restated, extended, supplemented or otherwise modified in writing from time to time, the "Credit Agreement"), receipt of a copy of which is hereby acknowledged by [the][each] Assignee. The Standard Terms and Conditions set forth in Annex 1 attached hereto are hereby agreed to and incorporated herein by reference and made a part of this Assignment and Assumption as if set forth herein in full.

For an agreed consideration, [the][each] Assignor hereby irrevocably sells and assigns to [the Assignee][the respective Assignees], and [the][each] Assignee hereby irrevocably purchases and assumes from [the Assignor][the respective Assignors], subject to and in accordance with the Standard Terms and Conditions and the Credit Agreement, as of the Effective Date inserted by the Administrative Agent as contemplated below (i) all of [the Assignor's][the respective Assignors'] rights and obligations in [its capacity as a Lender][their respective capacities as Lenders] under the Credit Agreement and any other documents or instruments delivered pursuant thereto to the extent related to the amount and percentage interest identified below of all of such outstanding rights and obligations of [the Assignor][the respective Assignors] and (ii) to the extent permitted to be assigned under applicable law, all claims, suits, causes of action and any other right of [the Assignor (in its capacity as a Lender)][the respective Assignors (in their respective capacities as Lenders)] against any Person, whether known or unknown, arising under or in connection with the Credit Agreement, any other documents or instruments delivered pursuant thereto or the loan transactions governed thereby or in any way based on or related to any of the foregoing, including, but not limited to, contract claims, tort claims, malpractice claims, statutory claims and all other claims at law or in equity related to the rights and obligations sold and assigned pursuant to clause (i) above (the rights and obligations sold and

For bracketed language here and elsewhere in this form relating to the Assignor(s), if the assignment is from a single Assignor, choose the first bracketed language. If the assignment is from multiple Assignors, choose the second bracketed language.

² For bracketed language here and elsewhere in this form relating to the Assignee(s), if the assignment is to a single Assignee, choose the first bracketed language. If the assignment is to multiple Assignees, choose the second bracketed language.

³ Select as appropriate.

⁴ Include bracketed language if there are either multiple Assignors or multiple Assignees.

assigned by [the][any] Assignor to [the][any] Assignee pursuant to clauses (i) and (ii) above being referred to herein collectively as [the][an] "Assignee
<u>Interest</u> "). Each such sale and assignment is without recourse to [the][any] Assignor and, except as expressly provided in this Assignment and
Assumption, without representation or warranty by [the][any] Assignor.

1.	Assignor(s):	_
2.	Assignee[s]:	-

[for each Assignee, indicate [Affiliate][Approved Fund] of [identify Lender]]

- 3. <u>Borrower(s)</u>: Harmony Biosciences, LLC
- 4. Administrative Agent: OrbiMed Royalty & Credit Opportunities III, LP, as the Administrative Agent under the Credit Agreement
- 5. <u>Credit Agreement</u>: Credit Agreement, dated as of January 9, 2020, by and among Harmony Biosciences, LLC, the Lenders party thereto, and OrbiMed Royalty & Credit Opportunities III, LP, as Administrative Agent
- 6. <u>Assigned Interest[s]</u>:

Assignor[s]5	A saigneofoli	Aggregate Amount of Loans for all Lenders ⁷	Amount of Loans Assigned	Percentage Assigned of Loans ⁸
Assignor[s]s	Assignee[s]6	Lodis for all Lenders/	Loans Assigned	
		\$	\$	%
		\$	\$	<u></u> %
		\$	\$	%

⁵ List each Assignor, as appropriate.

⁶ List each Assignee, as appropriate.

Amounts in this column and in the column immediately to the right to be adjusted by the counterparties to take into account any payments or prepayments made between the Trade Date and the Effective Date.

⁸ Set forth, to at least9 decimals, as a percentage of the Loans of all Lenders thereunder.

[7.	Trade	Date:	
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Effective Date: , 20 [TO BE INSERTED BY ADMINISTRATIVE AGENT AND WHICH SHALL BE THE EFFECTIVE DATE OF RECORDATION OF TRANSFER IN THE REGISTER THEREFOR.]

[SIGNATURE PAGES FOLLOW]

⁹ To be completed if the Assignor(s) and the Assignee(s) intend that the minimum as signment amount is to be determined as of the Trade Date.

	ASSIGNOR [NAME OF ASSIGNOR]
	By: Name: Title:
	ASSIGNEE [NAME OF ASSIGNEE]
	By:
	Name:
	Title:
[Signature Page to Assignment	and Assumption]

The terms set forth in this Assignment and Assumption are hereby agreed to:

ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, as Administrative Agent
By:
Name: Title:
Consented to:12
HARMONY BIOSCIENCES, LLC
By: Name:
Title:

Consented to:11

[Signature Page to Assignment and Assumption]

To be added only if the consent of the Administrative Agent is required by the terms of the Credit Agreement. To be added only if the consent of the Borrower is required by the terms of the Credit Agreement. 11

¹²

ANNEX 1 TO ASSIGNMENT AND ASSUMPTION

STANDARD TERMS AND CONDITIONS FOR

ASSIGNMENT AND ASSUMPTION

1. Representations and Warranties.

- 1.1. Assignor[s]. [The][Each] Assignor (a) represents and warrants that (i) it is the legal and beneficial owner of [the][the relevant] Assigned Interest, (ii) [the][such] Assigned Interest is free and clear of any lien, encumbrance or other adverse claim and (iii) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption and to consummate the transactions contemplated hereby; and (b) assumes no responsibility with respect to (i) any statements, warranties or representations made in or in connection with the Credit Agreement or any other Loan Document, (ii) the execution, legality, validity, enforceability, genuineness, sufficiency or value of the Loan Documents or any collateral thereunder, (iii) the financial condition of the Borrower, any of its Subsidiaries or Affiliates or any other Person of any of their respective obligations under any Loan Document.
- 1.2. Assignee[s]. [The][Each] Assignee (a) represents and warrants that (i) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption and to consummate the transactions contemplated hereby and to become a Lender under the Credit Agreement, (ii) it meets all the requirements to be an assignee under Section 10.10(b) of the Credit Agreement (subject to such consents, if any, as may be required under Section 10.10(b)(i)(B) and Section 10.10(b)(iii) of the Credit Agreement), (iii) from and after the Effective Date, it shall be bound by the provisions of the Credit Agreement as a Lender thereunder and, to the extent of [the][the relevant] Assigned Interest, shall have the obligations of a Lender thereunder, (iv) it is sophisticated with respect to decisions to acquire assets of the type represented by [the][such] Assigned Interest and either it, or the Person exercising discretion in making its decision to acquire [the][such] Assigned Interest, is experienced in acquiring assets of such type, (v) it has received a copy of the Credit Agreement, and has received or has been accorded the opportunity to receive copies of the most recent financial statements delivered pursuant to Section 7.1 thereof, as applicable, and such other documents and information as it deems appropriate to make its own credit analysis and decision to enter into this Assignment and Assumption and to purchase [the][such] Assigned Interest and (vi) it has, independently and without reliance upon the Administrative Agent or any other Lender and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Assignment and Assumption and to purchase [the][such] Assigned Interest; and (b) agrees that (i) it will, independently and without reliance upon the Administrative Agent, [the][any] Assignor or any other Lender, and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking action under the Loan Documents, and (ii) it will perform in accordance with their terms all of the obligations which by the terms of the Loan Documents are required to be performed by it as a Lender.

- 2. <u>Payments</u>. From and after the Effective Date, the Administrative Agent shall make all payments in respect of [the][each] Assigned Interest (including payments of principal, interest, fees and other amounts) to [the][the relevant] Assignor for amounts which have accrued to but excluding the Effective Date and to [the][the relevant] Assignee for amounts which have accrued from and after the Effective Date.
- 3. <u>General Provisions</u>. This Assignment and Assumption shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and assigns. This Assignment and Assumption may be executed in any number of counterparts, which together shall constitute one instrument. Delivery of an executed counterpart of a signature page of this Assignment and Assumption by telecopy shall be effective as delivery of a manually executed counterpart of this Assignment and Assumption. This Assignment and Assumption shall be governed by, and construed in accordance with, the law of the State of New York.

EXHIBIT G

THIS WARRANT AND THE SECURITIES PURCHASABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS, UNLESS AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

HARMONY BIOSCIENCES II, INC.

WARRANT

dated as of January 9, 2020 (the "Issue Date")

THIS CERTIFIES THAT, for value received, [] or its permitted successors or assigns (such Person and such permitted successors and assigns, each being the "Warrant Holder" with respect to the Warrant held by it), at any time and from time to time on any Business Day on or prior to 5:00 p.m. (New York City time), on the Expiration Date (as herein defined), is entitled (a) to subscribe for the purchase from Harmony Biosciences II, Inc., a Delaware corporation (the "Company"), [] Shares at a price per Share equal to the Exercise Price (as herein defined), and (b) to the other rights set forth herein; provided that the number of Shares issuable upon any exercise of this Warrant and the Exercise Price shall be adjusted and readjusted from time to time in accordance with Section 5. By accepting delivery hereof, the Warrant Holder agrees to be bound by the provisions hereof.

IN FURTHERANCE THEREOF, the Company irrevocably undertakes and agrees for the benefit of Warrant Holder as follows:

Section 1. Definitions and Construction.

- (a) Certain Definitions. As used herein (the following definitions being applicable in both singular and plural forms):
- "Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with such Person.
- "<u>Appraised Value</u>" means at any time the fair market value thereof determined in good faith by the Board of Directors of the Company as of a date which is within ten (10) days of the date as of which the determination is to be made, subject to Section 5(n).
- "Business Day" means any day except a Saturday, Sunday or other day on which commercial banks in New York, New York and Chicago, Illinois are authorized by law to close.
- "Charter" means the Company's Third Amended and Restated Certificate of Incorporation, as amended, or other constitutional document, as may be amended and restated or further amended from time to time.
- "Closing Price" means, for any trading day with respect to an Equity Security, (a) the last reported sale price on such day on the principal national securities exchange on which the Equity Securities are listed or admitted to trading or, if no such reported sale takes place on any such day, the average of the closing bid and asked prices thereon, as reported in The Wall Street Journal, or (b) if such Equity Securities shall not be listed or admitted to trading on a national securities exchange, the last reported sales price on the Nasdaq National Market System or, if no such reported sale takes place on any such day, the average of the closing bid and asked prices thereon, as reported in The Wall Street Journal, or (c) if such Equity Securities shall not be quoted on such National Market System nor listed or admitted to trading on a national securities exchange, then the average of the closing bid and asked prices, as reported by The Wall Street Journal for the over-the-counter market; provided that if clause (a), (b), or (c)

applies and no price is reported in The Wall Street Journal for any trading day, then the price reported in The Wall Street Journal for the most recent prior trading day shall be deemed to be the price reported for such trading day.

"Commission" means the Securities and Exchange Commission or any other Federal agency administering the Securities Act at the time.

"Common Stock" means the Company's currently authorized common stock, \$0.00001 par value per share, and stock of any other class or other consideration into which such currently authorized capital stock may hereafter have been changed.

"Convertible Security" has the meaning given to such term in the Charter.

"Corporate Reorganization" means any (i) merger, consolidation or reorganization or other similar transaction or series of related transactions which results in the voting securities of the Company outstanding immediately prior thereto representing immediately thereafter (either by remaining outstanding or by being converted into voting securities and/or other Equity Securities of the surviving or acquiring entity) 20% or less of the combined voting power of the voting securities of and economic interests in the Company or such surviving or acquiring entity outstanding immediately after such merger, consolidation or reorganization; (ii) sale, lease, exclusive license, transfer, conveyance or other disposition of all or substantially all of the assets of the Company; or (iii) sale of shares of Equity Securities of the Company by then-existing stockholders of the Company, in a single transaction or series of related transactions to a single person or entity, representing at least 80% of the voting power of the voting securities of and economic interests in the Company; provided, that with respect to subsections (i) and (iii) hereof, Options and value appreciation or similar rights shall be excluded from such calculations for all purposes.

"Equity Security" means any (i) common, preferred or other capital stock or similar security; (ii) warrants, options or other rights to, directly or indirectly, acquire any security described in clause (i) above; (iii) other security containing equity features or profit participation features; or (iv) security or instrument convertible or exchangeable, directly or indirectly, with or without consideration, into or for any security described in clauses (i) through (iii) above or any similar security

"Exchange Act" means the Securities Exchange Act of 1934, or any successor Federal statute, and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.

"Exercise Amount" means for any number of Warrant Shares as to which this Warrant is being exercised the product of (i) such number of Warrant Shares times (ii) the Exercise Price.

"Exercise Price" means \$1.96 per Share, as adjusted from time to time pursuant to Section 5.

"Expiration Date" means the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization.

"<u>Initial Holder</u>" means [

"IRA" means that certain Second Amended and Restated Investors' Rights Agreement, dated as of August 9, 2019, by and among the Company and each of the investors listed on Schedule A thereto, as may be amended from time to time.

"Market Price" on any day means (a) the unweighted average of the daily Closing Prices per Equity Security for the 20 consecutive trading days prior to such date or (b) if clauses (a), (b) and (c) of the definition of "Closing Price" are inapplicable, then the Appraised Value as of such day shall apply.

"Option" has the meaning given to such term in the Charter.

- "Person" means an individual, a corporation, a partnership, an association, a trust or any other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.
- "Requisite Holders" means at any time holders of Warrant Shares and Warrants representing at least a majority of the Warrant Shares outstanding or issuable upon the exercise of all the outstanding Warrants.
- "Securities Act" means the Securities Act of 1933, or any successor Federal statute, and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.
 - "Series C Stock" means the Company's Series C Preferred Stock, \$0.00001 par value per share, as presently constituted under the Charter.
- "<u>Shares</u>" means the Company's currently authorized Series C Stock, and following the applicable event pursuant to which a class or other form of consideration is issuable pursuant hereto, such stock of any other class or other consideration.
- "<u>Voting Agreement</u>" means the Second Amended and Restated Voting Agreement, dated as of August 9, 2019, by and among the Company and certain of its stockholders, as may be amended from time to time.
- "Warrant" means, as the context requires, this warrant and any successor warrant or warrants issued upon a whole or partial transfer or assignment of any such Share purchase warrant or of any such successor warrant.
- "<u>Warrant Shares</u>" means the number of Shares issued or issuable upon exercise of this Warrant as set forth in the introduction hereto, as adjusted from time to time pursuant to Section 5, or in the case of other Warrants, issuable upon exercise of those Warrants.
- (b) <u>Accounting Terms and Determinations</u>. Unless otherwise specified herein, all accounting terms used herein shall be interpreted, all accounting determinations hereunder shall be made, and all financial statements required to be delivered hereunder shall be prepared, in accordance with generally accepted accounting principles. When used herein, the term "financial statements" shall include the notes and schedules thereto. References to fiscal periods are to fiscal periods of the Company.
- (c) <u>Computation of Time Periods</u>. With respect to the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including" and the words "to" and "until" each mean "to but excluding." Periods of days shall be counted in calendar days unless otherwise stated.
- (d) <u>Construction</u>. Unless the context requires otherwise, references to the plural include the singular and to the singular include the plural, references to any gender include any other gender, the part includes the whole, the term "including" is not limiting, and the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or." The words "hereof," "herein," "hereby," "hereunder," and similar terms in this Warrant refer to this Warrant as a whole and not to any particular provision of this Warrant. Section, subsection, clause, exhibit and schedule references are to this Warrant, unless otherwise specified. Any reference to this Warrant includes any and all permitted alterations, amendments, changes, extensions, modifications, renewals, or supplements thereto or thereof, as applicable.
 - (e) Exhibits and Schedules. All of the exhibits and schedules attached hereto shall be deemed incorporated herein by reference.

(f) No Presumption Against Any Party. Neither this Warrant nor any uncertainty or ambiguity herein or therein shall be construed or resolved using any presumption against any party hereto or thereto, whether under any rule of construction or otherwise. On the contrary, this Warrant has been reviewed by each of the parties and their counsel and, in the case of any ambiguity or uncertainty, shall be construed and interpreted according to the ordinary meaning of the words used so as to fairly accomplish the purposes and intentions of all parties hereto.

Section 2. Exercise of Warrant.

- (a) Exercise and Payment. The Warrant Holder may exercise this Warrant in whole or in part, at any time or from time to time on any Business Day on or prior to the Expiration Date, by delivering to the Company a duly executed notice (a "Notice of Exercise") in the form of Exhibit A and (1) by payment to the Company of the Exercise Price per Warrant Share, at the election of the Warrant Holder, either (i) by wire transfer of immediately available funds to the account of the Company in an amount equal to the Exercise Amount, (ii) by receiving from the Company, in lieu of the entirety of the number of Warrant Shares for which the Warrant is being exercised, the number of Warrant Shares equal to (A) the number of Warrant Shares as to which this Warrant is being exercised minus (B) the number of Warrant Shares having a value, based on the Closing Price on the trading day immediately prior to the date of such exercise (or if there is no such Closing Price, then based on the Appraised Value as of such day), equal to the Exercise Amount, or (iii) any combination of the foregoing and (2) by surrender of this Warrant in accordance with Section 2(c). The Company acknowledges that the provisions of clause (ii) are intended, in part, to ensure that a full or partial exchange of this Warrant pursuant to such clause (ii) will qualify as a conversion, within the meaning of paragraph (d)(3)(ii) of Rule 144 under the Securities Act. At the request of any Warrant Holder, the Company will accept reasonable modifications to the exchange procedures provided for in this Section in order to accomplish such intent. For all purposes of this Warrant (other than this Section 2(a)), any reference herein to the exercise of this Warrant shall be deemed to include a reference to the exchange of this Warrant into Shares in accordance with the terms of clause (ii).
- (b) <u>Effectiveness and Delivery.</u> As soon as practicable but not later than five Business Days after the Company shall have received such Notice of Exercise and payment, the Company shall execute and deliver or cause to be executed and delivered, in accordance with such Notice of Exercise, a certificate or certificates representing the number of Shares specified in such Notice of Exercise, issued in the name of the Warrant Holder or in such other name or names of any Person or Persons designated in such Notice of Exercise so long as such transferor and transferee have complied with all transfer provisions contained herein. This Warrant shall be deemed to have been exercised and such Share certificate or certificates shall be deemed to have been issued, and the Warrant Holder or other Person or Persons designated in such Notice of Exercise shall be deemed for all purposes to have become a holder of record of Shares, all as of the date that such Notice of Exercise and payment shall have been received by the Company.
- (c) <u>Surrender of Warrant</u>. The Warrant Holder shall surrender this Warrant to the Company when it delivers the Notice of Exercise, and in the event of a partial exercise of the Warrant, the Company shall execute and deliver to the Warrant Holder, at the time the Company delivers the Share certificate or certificates issued pursuant to such Notice of Exercise, a new Warrant for the unexercised portion of the Warrant, but in all other respects identical to this Warrant.

(d) <u>Legend</u>. Each certificate for Warrant Shares issued upon exercise of this Warrant, unless at the time of exercise such Warrant Shares are registered under the Securities Act, shall bear the following legend:

THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS, UNLESS AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

Any certificate for Warrant Shares issued at any time in exchange or substitution for any certificate bearing such legend (unless at that time such Warrant Shares are registered under the Securities Act) shall also bear such legend unless, in the written opinion of counsel selected by the holder of such certificate (who may be an employee of such holder), which counsel and opinion shall be reasonably acceptable to the Company, the Warrant Shares represented thereby need no longer be subject to restrictions on resale under the Securities Act.

- (e) <u>Fractional Shares</u>. The Company shall not be required to issue fractions of Shares upon an exercise of the Warrant. If any fraction of a Share would, but for this restriction, be issuable upon an exercise of the Warrant, in lieu of delivering such fractional Share, the Company shall pay to the Warrant Holder, in cash, an amount equal to the same fraction times the Closing Price on the trading day immediately prior to the date of such exercise (or if there is no such Closing Price, then based on the Appraised Value as of such day).
- (f) Expenses and Taxes. The Company shall pay all expenses, taxes and owner charges payable in connection with the preparation, issuance and delivery of certificates for the Warrant Shares and any new Warrants, except that if the certificates for the Warrant Shares or the new Warrants are to be registered in a name or names other than the name of the Warrant Holder, funds sufficient to pay all transfer taxes payable as a result of such transfer shall be paid by the Warrant Holder at the time of its delivery of the Notice of Exercise or promptly upon receipt of a written request by the Company for payment.
- (g) <u>Automatic Cashless Exercise</u>. To the extent that there has not been an exercise by the Warrant Holder pursuant to Section 2(a) hereof, any portion of the Warrant that remains unexercised shall be exercised automatically in whole (not in part), upon the Expiration Date. Payment by the Warrant Holder upon such automatic exercise shall be in the form of the Warrant Holder receiving from the Company, in lieu of the full number of Warrant Shares, the number of Warrant Shares equal to (i) the number of Warrant Shares as to which this Warrant is being automatically exercised minus (ii) the number of Warrant Shares having a value, based on the Closing Price on the trading day immediately prior to the date of such automatic exercise (or if there is no such Closing Price, then based on the Appraised Value as of such day), equal to the Exercise Amount.

Section 3. Investment Representation. By accepting the Warrant, the Warrant Holder represents that (a) it is acquiring the Warrant for its own account for investment purposes and not with the view to any sale or distribution, (b) the Warrant Holder will not offer, sell or otherwise dispose of the Warrant or the Warrant Shares except under circumstances as will not result in a violation of applicable securities laws, (c) the Warrant Holder is an "accredited investor" as that term is defined in Rule 501 under the Securities Act, (d) the Warrant Holder has had such opportunity as it has deemed adequate to ask questions of the Company and its representatives and to otherwise obtain from the Company such information regarding the Company, along with copies of all information from the Company that the Warrant Holder deems necessary to permit it to evaluate the merits of accepting this Warrant, (e) the Warrant Holder has such knowledge, sophistication and experience in business and financial matters to be able to evaluate the merits, risks and other considerations relating to the acquisition of this Warrant; (f) the Warrant Holder understands and acknowledges that this Warrant involves a high degree of risk; and (g) the Warrant Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Securities Act, or the securities or similar laws of any jurisdiction and are offered in reliance on exemptions therefrom, which reliance depends upon, among other things, the bona fide nature of the investment intent and the truth and accuracy of Warrant Holder's representations as expressed herein. Immediately upon acceptance of this Warrant, the Warrant Holder shall execute and deliver to the Company a counterpart to the IRA and acknowledges and agrees that the Warrant Holder shall be an "Investor" for all purposes thereunder and shall be bound thereby. Upon any exercise of this Warrant or other issuance of Warrant Shares (including, without limitation, pursuant to Section 2(g) or 5(e)), the Warrant Holder shall execute and deliver to the Company a counterpart to the Voting Agreement and agrees that the Warrant Holder shall be an "Investor" and a "Stockholder" for all purposes thereunder and shall be bound thereby; provided that, notwithstanding the foregoing, the Warrant Holder shall not be required to become a party to the Voting Agreement if the Voting Agreement (i) does not provide for the Warrant Holder to become a party to such agreement in accordance with its terms (and without the need to obtain the consent of any other person or entity) at the time of such exercise or conversion or (ii) has been amended since the date hereof in a manner that would have a disproportionate adverse effect on the Warrant Holder as compared to other parties thereto.

Section 4. Validity of Warrant and Issuance of Shares.

- (a) The Company represents and warrants that this Warrant has been duly authorized, is validly issued, and constitutes the valid and binding obligation of the Company.
- (b) The Company further represents and warrants that on the date hereof it has duly authorized and reserved, and the Company hereby agrees that it will at all times until the Expiration Date have duly authorized and reserved, such number of Shares as will be sufficient to permit the exercise in full of the Warrant, and that all such Shares are and will be duly authorized and, when issued upon exercise of the Warrant, will be validly issued, fully paid and non-assessable, and free and clear of all security interests, claims, liens, equities and other encumbrances.

Section 5. Antidilution Provisions; Other Significant Events.

(a) <u>Share Reorganization</u>. If prior to exercise of this Warrant and the Expiration Date, the Company shall subdivide its outstanding Shares into a greater number of Shares, by way of a stock split, stock dividend or otherwise, or consolidate its outstanding Shares into a smaller number of Shares (any such event being herein called a "<u>Share Reorganization</u>"), then (i) the Exercise Price shall be adjusted, effective immediately after the effective date of such Share Reorganization, to a price determined by multiplying the Exercise Price in effect immediately prior to such effective date by a fraction, the numerator of which shall be the number of Shares outstanding on such effective date before giving effect to such Share Reorganization and the denominator of which shall be the number of Shares outstanding

after giving effect to such Share Reorganization, and (ii) the number of Shares subject to purchase upon exercise of this Warrant shall be adjusted, effective at such time, to a number determined by multiplying the number of Shares subject to purchase immediately before such Share Reorganization by a fraction, the numerator of which shall be the number of Shares outstanding after giving effect to such Share Reorganization and the denominator of which shall be the number of Shares outstanding immediately before giving effect to such Share Reorganization.

- (b) <u>Antidilution Rights Under the Charter</u>. The Shares are subject to antidilution rights as set forth in the Charter. The Company shall promptly provide the Warrant Holder with any restatement, amendment or modification to, or waiver of, the Charter; <u>provided</u> that no such restatement, amendment, modification or waiver shall impair or reduce the antidilution rights applicable to the Shares under the Charter as of the date hereof unless such restatement, amendment, modification or waiver affects the rights of the Warrant Holder with respect to the Shares in the same manner as it affects all other holders of such Shares.
- (c) "Pay to Play" Rights. In the event that any terms or conditions that require a holder of the Shares to purchase securities in a future round of Equity Security financing or else lose the benefit of antidilution protections or other rights applicable to the Shares or have such Shares automatically convert into Common Stock or another class or series of capital stock in the Charter are triggered in connection with any future round of Equity Security financing (a "Trigger Event"), then, in each such event, the purchase rights under this Warrant shall automatically adjust to provide the Warrant Holder, upon the later exercise hereof, with the same securities and/or rights that the Warrant Holder would have received had the Warrant Holder (x) exercised this Warrant prior to such Trigger Event pursuant to Section 2(a)(ii), and (y) participated in the applicable Equity Security financing in an amount sufficient to be deemed to have fully participated for purposes of such "pay to play" provision.

(d) Special Distributions; Above Market Purchases of Securities.

- (i) If the Company shall issue or distribute to any holder or holders of Shares evidences of indebtedness, any other securities of the Company or any cash, property or other assets (excluding (x) a Share Reorganization and (y) another issuance, sale or other distribution of Shares), whether or not accompanied by a purchase, redemption or other acquisition of Shares (any such nonexcluded event being herein called a "Special Distribution"), then (A) upon any exercise of this Warrant, the Warrant Holder shall be entitled to a pro-rata share of such Special Distribution as though the Warrant Holder had exercised this Warrant to such extent immediately prior to the record date for such Special Distribution or (B) upon the closing of a Corporate Reorganization, the Warrant Holder shall be entitled to such Special Distribution as though the Warrant Holder had exercised this Warrant pursuant to Section 2(a)(ii) immediately prior to the record date for such Special Distribution. A reclassification of the Shares (other than a change in par value, or from par value to no par value or from no par value to par value) into shares of any other class of stock shall be deemed to be a distribution by the Company to the holders of its Shares of such class of stock and, if the outstanding Shares shall be changed into a larger or smaller number of Shares as part of such reclassification, a Share Reorganization.
- (ii) If, at any time after the date hereof, the Company or any subsidiary of the Company shall repurchase (a "Repurchase"), by self-tender offer or otherwise, any securities of the Company at an aggregate repurchase price that exceeds the aggregate Market Price for the securities repurchased determined as of the Business Day immediately prior to the earliest of (x) the date of such Repurchase, (y) the commencement of an offer to repurchase or (z) the public announcement of either

(such date being referred to as the "<u>Determination Date</u>"), then the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant shall be adjusted as follows:

(A) The Exercise Price shall be reduced to an amount equal to the product of (I) the Exercise Price in effect immediately prior to such issuance or sale times (II) a fraction, (aa) the numerator of which shall be (x) the product of (1) the aggregate Market Price for the Equity Securities of the Company as of the Determination Date times (2) the number of Equity Securities of the Company outstanding immediately following the consummation of the Repurchase (on an as-converted to Common Stock basis) less (y) the Repurchase Premium (as defined below), and (bb) the denominator of which shall be (x) the product of (1) the aggregate Market Price for the Equity Securities of the Company as of the Determination Date times (2) the number of Equity Securities of the Company outstanding immediately following the consummation of the Repurchase (on an as-converted to Common Stock basis).

(B) The number of Warrant Shares issuable upon exercise of this Warrant shall be increased to the number of Shares determined by multiplying (x) the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such distribution times (y) a fraction (1) the numerator of which shall be the Exercise Price in effect immediately prior to the adjustment in clause (A) of this Section 5(d)(ii) and (2) the denominator of which shall be the Exercise Price in effect immediately after such adjustment.

The amount by which the aggregate repurchase price for all securities repurchased in any Repurchase (including for such purposes any fees or other direct or indirect consideration payable in connection therewith) exceeds the aggregate Market Price for such securities is referred to as the "Repurchase Premium." Notwithstanding the foregoing, the provisions of this Section 5(d)(ii) shall not apply to any purchase of any securities of the Company that (x) are expressly authorized pursuant to the Charter or (y) are in connection with the termination of employment of an employee of the Company or a subsidiary thereof or the termination of service of a board member, consultant or advisor of the Company or a subsidiary thereof pursuant to the terms and conditions of the applicable award or other agreement or an equity incentive plan, agreement or arrangement approved by the Board of Directors of the Company; provided, that any such repurchase pursuant to the preceding clause (y) (i) is not for an amount in excess of the fair market value of such Equity Securities, as determined by the Company's Board of Directors or a committee thereof, based on a third-party valuation that was given on or since the end of the most recent calendar quarter and (ii) the Warrant Holder may not contest or dispute the repurchase price associated therewith, so long as the other requirements of this clause (y) were complied with.

(e) <u>Corporate Reorganization</u>. In connection with a Corporate Reorganization, the Company shall cause this Warrant to be exchanged for the consideration that Warrant Holder would have received if Warrant Holder had chosen to exercise its right to have Shares issued pursuant to Section 2(a) (ii) without actually exercising such right, acquiring such Shares and exchanging such Shares for such consideration.

(f) Adjustment Rules.

- (i) Any adjustments pursuant to this Section 5 shall be made successively whenever any event referred to herein shall occur.
- (ii) No adjustments shall be made pursuant to this Section 5 in respect of the issuance of Warrant Shares upon exercise of the Warrant.
- (iii) If the Company shall take a record of the holders of its Shares for any purpose referred to in this Section 5, then (x) such record date shall be deemed to be the date of the issuance, sale, distribution or grant in question and (y) if the Company shall legally abandon such action prior to effecting such action, no adjustment shall be made pursuant to this Section 5 in respect of such action.

(iv) In computing adjustments under this Section 5, (A) fractional interests in Shares shall be taken into account to the nearest one-thousandth of a Share, and (B) calculations of the Exercise Price shall be carried to the nearest one-thousandth of one cent.

(g) Redemption or Conversion of Shares.

- (i) If all of the Shares are redeemed by the Company at any time prior to the exercise of this Warrant or the Expiration Date, the Company shall, at the closing of such redemption, exchange this Warrant for the consideration that Warrant Holder would have received if Warrant Holder had chosen to exercise its right to have Shares issued pursuant to Section 2(a)(ii) immediately prior to such redemption without actually exercising such right, acquiring such Shares and having such Shares redeemed and the Warrant Holder shall accept such amount as payment in full for its rights under this Warrant.
- (ii) If the Series C Stock is converted into Common Stock, this Warrant shall automatically convert into the right to receive the number of shares of Common Stock that the Warrant Holder would have received if it had exercised this Warrant in full immediately prior to the conversion of Series C Stock into Common Stock (such number of shares of Common Stock issuable upon on such exercise, the "Common Stock Number") and the Exercise Price per share of Common Stock shall be an amount equal to the Exercise Amount divided by the Common Stock Number, in each case, subject to further adjustment pursuant to this Section 5 (other than Section 5(b)). The provisions of Section 5 (other than this Section 5(g)) shall not apply to the conversion of Series C Stock into Common Stock and the provisions of Section 5(b) shall not apply to any transaction or event thereafter.
- (h) <u>Proceedings Prior to Any Action Requiring Adjustment</u>. As a condition precedent to the taking of any action which would require an adjustment or readjustment pursuant to this Section 5, the Company shall take any action which may be necessary, including obtaining regulatory approvals or exemptions (in each case, other than any such approvals or exemptions necessitated by the Warrant Holder's regulatory status), in order that the Company may thereafter validly and legally issue as fully paid and nonassessable all Shares which the Warrant Holder is entitled to receive upon exercise of the Warrant.
- (i) <u>Notice of Adjustment</u>. Not less than 10 days prior to the record date or effective date, as the case may be, of any action which requires or might require an adjustment pursuant to this Section 5, the Company shall give notice to the Warrant Holder of such event, describing such event in reasonable detail and specifying the record date or effective date, as the case may be, and, if determinable, the required adjustment and computation thereof. If the required adjustment is not determinable as of the time of such notice, the Company shall give notice to the Warrant Holder of such adjustment and computation as soon as reasonably practicable after such adjustment becomes determinable.
- (j) <u>Subsequent Warrants</u>. Irrespective of any adjustments in the Exercise Price or the number of Warrant Shares issuable upon exercise of this Warrant, any successor or replacement warrants issued theretofore or thereafter may continue to express the same Exercise Price per Share and number and kind of Warrant Shares as are stated in this Warrant.
- (k) <u>Disputes</u>. If the Requisite Holders dispute the calculation of the adjusted Exercise Price or adjusted Warrant Shares issuable upon exercise, the Requisite Holders shall deliver prompt written notice thereof to the Company (in any event, within 20 calendar days of notice from the Company of the calculation of adjusted Exercise Price or adjusted Warrant Shares), together with the Requisite Holders' calculation of the adjusted Exercise Price or adjusted Warrant Shares, as applicable. Such disputed item shall be determined by the independent auditors of the Company, and such determination shall be binding

upon the Company and the holders of the Warrants and the Warrant Shares if made in good faith and without manifest error. The fees of the independent auditors of the Company in connection with any such dispute shall be paid by the Company, unless the Company's calculation of the disputed item(s) was accurate, in which case the fees of the independent auditors of the Company shall be paid by the Requisite Holders.

(l) Other Actions Affecting Shares.

- (i) Equitable Equivalent. In case any event shall occur as to which the provisions of this Section 5 set forth above hereof are not strictly applicable but the failure to make any adjustment would not, in the opinion of the Warrant Holder, fairly protect the purchase rights represented by this Warrant in accordance with the essential intent and principles of this Section 5, then, in each such case, at the request of the Warrant Holder, the Company shall appoint a firm of independent investment bankers of recognized national standing (which shall be completely independent of the Company and shall be reasonably satisfactory to the Warrant Holder or the Requisite Holders), which shall give their opinion upon the adjustment, if any, on a basis consistent with the essential intent and principles established in this Section 5, necessary to preserve, without dilution, the purchase rights represented by this Warrant. Upon receipt of such opinion, the Company will promptly mail a copy thereof to the holder of this Warrant and shall make the adjustments described therein. The fees of the independent investment bankers in connection with any such dispute shall be paid by the Company, unless the independent investment banker determines that no adjustment is necessary, in which case the fees of such independent investment banker shall be paid by such Warrant Holder.
- (ii) No Avoidance. The Company shall not, by amendment of its Charter or by-laws or through any consolidation, merger, reorganization, transfer of assets, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the holder of this Warrant against dilution or other impairment as if the holder was a shareholder of the Company entitled to the benefit of fiduciary duties afforded to shareholders under Delaware law.
- (m) <u>Adjustment of Par Value</u>. If for any reason (including the operation of the adjustment provisions set forth in this Warrant), the Exercise Price on any date of exercise of this Warrant shall not be lawful and adequate consideration for the issuance of the relevant Warrant Shares, then the Company shall take such steps as are necessary (including the amendment of its Charter so as to reduce the par value of the Shares) to cause such Exercise Price to be adequate and lawful consideration on the date the payment thereof is due, but if the Company shall fail to take such steps, then the Company acknowledges that the Warrant Holder shall have been damaged by the Company in an amount equal to an amount, which, when added to the total Exercise Price for the relevant Warrant Shares, would equal lawful and adequate consideration for the issuance of such Warrant Shares, and the Company irrevocably agrees that if the Warrant Holder shall then forgive the right to recover such damages from the Company, such forgiveness shall constitute, and Company shall accept such forgiveness as, additional lawful consideration for the issuance of the relevant Warrant Shares.

(n) Appraisal.

(i) If the Requisite Holders shall, for any reason whatsoever, disagree with the Company's determination of the Appraised Value of a Share, then such holders shall by notice to the Company (an "Appraisal Notice") given within sixty (60) days after the Company notifies the holders of such determination, elect to dispute such determination, and such dispute shall be resolved as set forth in clause (ii) of this Section.

(ii) The Company shall within ten (10) days after an Appraisal Notice shall have been given, select and engage an independent investment bank of national repute (the "Appraiser") (which shall be completely independent of the Company and shall be reasonably satisfactory to the holder or the Requisite Holders), pursuant to an engagement letter between the Company and the Appraiser with respect to such valuation in form and substance reasonably acceptable to Requisite Holders, to make an independent determination of the Appraised Value of a Share; such value shall be determined without deduction for (a) liquidity considerations, (b) minority shareholder status, or (c) any liquidation or other preference or any right of redemption in favor of any other equity securities of the Company. The costs of engagement of such investment bank for any such determination of Appraised Value shall be paid by the Company unless the Appraiser concurs with the Company's determination of Appraised Value, in which case, the Requisite Holders shall pay the costs of engagement of such investment bank related to the determination of Appraised Value.

Section 6. <u>Transfer of Warrant</u>. The Warrant Holder may only transfer this Warrant or any Shares issued with respect hereto (a) to an Affiliate of such Warrant Holder (and if such transferee fails at any time to remain an Affiliate of the original Warrant Holder, such transferee shall be obligated to transfer the Warrant or the Shares issued with respect thereto, as applicable, to the original Warrant Holder or an Affiliate thereof absent consent of the Company's Board of Directors) or (b) in compliance with the provisions of the IRA. The Warrant Holder upon transfer of the Warrant must deliver to the Company a duly executed Warrant Assignment in the form of <u>Exhibit B</u> and upon surrender of this Warrant to the Company, the Company shall execute and deliver a new Warrant with appropriate changes to reflect such assignment, in the name or names of the assignee or assignees specified in the Warrant Assignment or other instrument of assignment and, if the Warrant Holder's entire interest is not being transferred or assigned, in the name of the Warrant Holder, and upon the Company's execution and delivery of such new Warrant, this Warrant shall promptly be cancelled; and <u>provided</u> that any assignee shall have all of the rights of an Initial Holder hereunder. The Warrant Holder shall pay any transfer tax imposed in connection with such assignment (if any). Any transfer or exchange of this Warrant shall be without charge to the Warrant Holder (except as provided above with respect to transfer taxes, if any) and any new Warrant issued shall be dated the date hereof.

Section 7. <u>Assistance in Disposition of Warrant or Warrant Shares</u>. Notwithstanding any other provision herein, in the event that it becomes unlawful for the Warrant Holder to continue to hold the Warrant, in whole or in part, or some or all of the Shares held by it, or restrictions are imposed on any the Warrant Holder by any statute, regulation or governmental authority which, in the judgment of the Warrant Holder, make it unduly burdensome to continue to hold the Warrant or such Shares, the Warrant Holder may sell or otherwise dispose of the Warrant (subject to the restrictions on transfer provided in the IRA) or its Shares, and the Company agrees to provide reasonable assistance to the Warrant Holder in disposing of the Warrant and such Shares in a prompt and orderly manner and, at the request of the Warrant Holder, to provide (and authorize the Warrant Holder to provide) financial and other information concerning the Company to any prospective purchaser of the Warrant or Shares owned by the Warrant Holder, subject to a customary confidentiality agreement.

Section 8 Covenants. The Company agrees that:

(a) <u>Amendments of Organizational Documents</u>. Upon request of the Warrant Holder in connection with any proposed registration hereunder of Warrant Shares held by the Warrant Holder and for purposes of complying with any law or regulation applicable to the Warrant Holder which shall be confirmed by an opinion of counsel for the Warrant Holder, the Company will amend its Charter or other organizational documents (such amendment to be satisfactory in form and substance to the Warrant Holder), and take such other action as is necessary, to provide for the issuance of a class of nonvoting Shares, the holders of which will have identical rights to those of the holders of the Shares, except for

voting rights, and to the effect that the Warrant Holder or any of its Affiliates, as holders of such non-voting Shares shall not have the right to exchange and convert such units for Shares but that any transferee of the Warrant Holder or any of its Affiliates shall have the right to exchange and convert such units for Shares. If the Charter or other organizational documents of the Company so amended upon the request of the Warrant Holder, any Warrants still held by the Warrant Holder after the registration of any of its Warrant Shares shall be deemed to be Warrants for the purchase of such Shares but otherwise shall have the same rights and benefits as the original Warrant.

- (b) <u>Structural Dilution</u>. So long as this Warrant remains outstanding, the Company shall not permit any of its subsidiaries to issue, sell, distribute or otherwise grant in any manner (including by assumption) any rights to subscribe for or to purchase, or any warrants or options for the purchase of any equity securities of such subsidiary or any securities convertible into or exchangeable for such equity securities (or any rights to subscribe for or to purchase, or any warrants or options for the purchase of any such convertible or exchangeable securities), whether or not immediately exercisable or exercisable prior to the Expiration Date or thereafter.
 - (c) Notices Of Corporate Action or Notice to or from Holders of Series C Stock. In the event of:
- (i) any taking by the Company of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any distribution, or any right to subscribe for, purchase or otherwise acquire any Shares or any other securities or property, or to receive any other right, or
- (ii) any capital reorganization of the Company, any reclassification or recapitalization of the capital stock of the Company, any consolidation or merger involving the Company and any other Person or any transfer of all or substantially all the assets of the Company to any other Person, or any Corporate Reorganization, or
 - (iii) any voluntary or involuntary dissolution, liquidation or winding-up of the Company,
 - (iv) any issuance of any Equity Securities, Shares, Convertible Security or Option by the Company, or
 - (v) any notice given by the Company to the holders of Series C Stock or given by the holders of Series C Stock to the Company

the Company will mail to the Warrant Holder a notice specifying (i) the date or expected date on which any such record is to be taken for the purpose of such dividend, distribution or right, and the amount and character of such dividend, distribution or right, (ii) the date or expected date on which any such reorganization, reclassification, recapitalization, consolidation, merger, transfer, dissolution, liquidation or winding-up is to take place, (iii) the time, if any such time is to be fixed, as of which the holders of record of Shares (or other securities under Section 5(d)) shall be entitled to exchange their Shares (or other securities under Section 5(d)) for the securities or other property deliverable upon such reorganization, reclassification, recapitalization, consolidation, merger, transfer, dissolution, liquidation or winding-up and a description in reasonable detail of the transaction, (iv) the date of such issuance, together with a description of the security so issued and the consideration received by the Company therefor and (v) the date on which the notice was given or received by the Company. Other than with respect to notices given to the holders of Series C Stock or given by the holders of Series C Stock, which shall be provided concurrently with such distributions, such notice shall be mailed at least ten (10) days prior to the date therein specified.

Section 9. <u>Lost, Mutilated or Missing Warrants</u>. Upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of any Warrant, and, in the case of loss, theft or destruction, upon receipt of indemnification satisfactory to the Company (in the case of an Initial Holder its unsecured, unbonded agreement of indemnity shall be sufficient) or, in the case of mutilation, upon surrender and cancellation of the mutilated Warrant, the Company shall execute and deliver a new Warrant of like tenor and representing the right to purchase the same aggregate number of Warrant Shares (subject to adjustment pursuant to Section 5).

Section 10. Waivers; Amendments. Any provision of this Warrant may be amended or waived with (but only with) the written consent of the Company and the Requisite Holders; provided that no such amendment or waiver shall, without the written consent of the Company and the Warrant Holder, (a) change the number of Warrant Shares issuable upon exercise of the Warrant or the Exercise Price, (b) shorten the Expiration Date, or (c) amend, modify or waive the provisions of this Section or the definition of "Requisite Holders." Any amendment or waiver effected in compliance with this Section shall be binding upon the Company and the Warrant Holder. The Company shall give prompt notice to the Warrant Holder of any amendment or waiver effected in compliance with this Section. No failure or delay of the Company or the Warrant Holder in exercising any power or right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such a right or power, preclude any other or further exercise thereon or the exercise of any other right or power. No notice or demand on the Company in any case shall entitle the Company to any other or future notice or demand in similar or other circumstances. The rights and remedies of the Company and the Warrant Holder hereunder are cumulative and not exclusive of any rights or remedies which it would otherwise have.

Section 11. Miscellaneous.

- (a) <u>Shareholder Rights</u>. The Warrant shall not entitle any Warrant Holder, prior to the exercise of the Warrant, to any voting rights as a shareholder of the Company.
- (b) <u>Expenses</u>. The Company shall pay all reasonable expenses of the Warrant Holder, including reasonable fees and disbursements of counsel, in connection with the preparation of the Warrant, or any waiver, consent, amendment or modification hereof if such waiver, consent, amendment or modification is proposed by the Company (regardless of whether the same becomes effective), or the successful enforcement of the provisions hereof; <u>provided</u> that the Company shall not be required to pay any expenses of the Warrant Holder arising solely in connection with a transfer of the Warrant.
- (c) <u>Successors and Assigns</u>. All the provisions of this Warrant by or for the benefit of the Company or the Warrant Holder shall bind and inure to the benefit of their respective successors and assigns.
- (d) <u>Severability</u>. In case any one or more of the provisions contained in this Warrant shall be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby. The parties shall endeavor in good faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provisions.

- (e) <u>Notices</u>. Any notice or other communication hereunder shall be in writing and shall be sufficient if sent by first-class mail or courier, postage prepaid, and addressed as follows: (a) if to the Company, addressed to the Company at its address for notices as set forth below its signature hereon or any other address as the Company may hereafter notify to the Warrant Holder and (b) if to the Warrant Holder, addressed to such address as the Warrant Holder may hereafter from time to time notify to the Company for the purposes of notice hereunder.
- (f) <u>Equitable Remedies</u>. Without limiting the rights of the Company and the Warrant Holder to pursue all other legal and equitable rights available to such party for the other parties' failure to perform its obligations hereunder, the Company and the Warrant Holder each hereto acknowledge and agree that the remedy at law for any failure to perform any obligations hereunder would be inadequate and that each shall be entitled to specific performance, injunctive relief or other equitable remedies in the event of any such failure.
- (g) <u>Governing Law</u>. THIS WARRANT SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF DELAWARE, EXCEPT AS OTHERWISE REQUIRED BY MANDATORY PROVISIONS OF LAW.
- (h) Forum Selection and Consent to Jurisdiction. ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, THE WARRANT, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE COMPANY OR ANY WARRANT HOLDER IN CONNECTION HEREWITH OR THEREWITH SHALL BE BROUGHT AND MAINTAINED IN THE DELAWARE COURT OF CHANCERY OR IN THE UNITED STATES DISTRICT COURT FOR THE STATE OF DELAWARE. EACH PARTY HERETO IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF DELAWARE AT THE ADDRESS FOR NOTICES SPECIFIED IN SECTION 11(E). EACH PARTY HERETO HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY HAVE OR HEREAFTER MAY HAVE TO THE LAYING OF VENUE OF ANY SUCH LITIGATION BROUGHT IN ANY SUCH COURT REFERRED TO ABOVE AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM. TO THE EXTENT THAT ANY PARTY HERETO HAS OR HEREAFTER MAY ACQUIRE ANY IMMUNITY FROM JURISDICTION OF ANY COURT OR FROM ANY LEGAL PROCESS (WHETHER THROUGH SERVICE OR NOTICE, ATTACHMENT PRIOR TO JUDGMENT, ATTACHMENT IN AID OF EXECUTION OR OTHERWISE) WITH RESPECT TO ITSELF OR ITS PROPERTY, SUCH PARTY HEREBY IRREVOCABLY WAIVES TO THE FULLEST EXTENT PERMITTED BY LAW SUCH IMMUNITY IN RESPECT OF ITS OBLIGATIONS UNDER THE WARRANT.
- (i) <u>WAIVER OF JURY TRIAL</u>. THE COMPANY AND THE WARRANT HOLDER HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVE TO THE FULLEST EXTENT PERMITTED BY LAW ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, THE WARRANT, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE COMPANY OR ANY WARRANT HOLDER IN CONNECTION THEREWITH. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT IT HAS RECEIVED FULL AND SUFFICIENT CONSIDERATION FOR THIS PROVISION (AND EACH OTHER PROVISION OF THE WARRANT) AND THAT THIS PROVISION IS A MATERIAL INDUCEMENT FOR THE OTHER PARTIES HERETO ENTERING INTO THE WARRANT.

- (j) <u>Section Headings</u>. The section headings used herein are for convenience of reference only and shall not be construed in any way to affect the interpretation of any provisions of the Warrant.
- (k) Execution in Counterparts. This Warrant may be executed by the parties hereto in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. Delivery of an executed counterpart of a signature page to this Warrant by email (e.g., "pdf" or "tiff") or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Warrant to be execut the day and year first written above.	ed by their respective officers thereunto duly authorized as of
	Harmony Biosciences II, Inc., a Delaware corporation
	Ву
	Name:
	Title:
	Address for Notices:
	Telephone:
	Facsimile:
	[WARRANT HOLDER]
	Ву
	Name:
	Title:
	1100.

Address for Notices:

Telephone: Facsimile:

Exhibit A to Warrant

Form of Notice of Exercise

	, 20
Го: []	
Reference is made to the Warrant dated, 20 Terms defined therein are use	ed herein as therein defined.
The undersigned, pursuant to the provisions set forth in the Warrant, hereby irrevocanakes payment herewith in full therefor at the Exercise Price of \$ in the following for	·
[If the number of Shares as to which the Warrant is being exercised is less than all o equests that a new Warrant representing the remaining balance of the Shares be registered]	
The undersigned hereby represents that it is exercising the Warrant for its own account with the view to any sale or distribution and that the Warrant Holder will not offer, sel Warrant Shares in violation of applicable securities laws.	
	[NAME OF WARRANT HOLDER]
	Ву
	Name: Title:
	[ADDRESS OF WARRANT HOLDER]

Exhibit B to Warrant

Form of Warrant Assignment

Reference is made to the Warrant dated , 20 , issued by Harmony Biosciences II, Inc. Terms defined therein are used herein as therein defined.

FOR VALUE RECEIVED in accordance with Section 6 of the Warrant, (the "Assignor") hereby sells, assigns and transfers all of the rights of the Assignor as set forth in such Warrant, with respect to the number of Warrant Shares covered thereby as set forth below, to the Assignee(s) as set forth below:

Number of Warrant Shares

Name(s) of Assignee(s)	Address(es)	Number of Warrant Shares

All notices to be given by the Company to the Assignor as Warrant Holder shall be sent to the Assignee(s) at the above listed address(es), and, if the number of Shares being hereby assigned is less than all of the Shares covered by the Warrant held by the Assignor, then also to the Assignor.

In accordance with Section 6 of the Warrant, the Assignor requests that the Company execute and deliver a new Warrant or Warrants in the name or names of the assignee or assignees, as is appropriate, or, if the number of Shares being hereby assigned is less than all of the Shares covered by the Warrant held by the Assignor, new Warrants in the name or names of the assignee or the assignees, as is appropriate, and in the name of the Assignor.

The undersigned represents that the Assignee has represented to the Assignor that the Assignee is acquiring the Warrant for its own account or the account of an Affiliate for investment purposes and not with the view to any sale or distribution, and that the Assignee will not offer, sell or otherwise dispose of the Warrant or the Warrant Shares except under circumstances as will not result in a violation of applicable securities laws.

Dated: , 20

[NAME OF ASSIGNOR]
By Name: Title:
[ADDRESS OF ASSIGNOR]

PLEDGE AND SECURITY AGREEMENT

This PLEDGE AND SECURITY AGREEMENT, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, this "Security Agreement"), is made by HARMONY BIOSCIENCES LLC, a Delaware limited liability company (the "Borrower"), HARMONY BIOSCIENCES II, INC., a Delaware corporation, ("Holdings") (the Borrower and Holdings, together with any other entity that may become a party hereto as provided herein, are referred to each as a "Grantor" and, collectively as the "Grantors"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, as Administrative Agent (the "Administrative Agent") for the Secured Parties (defined below).

<u>WITNESSETH</u>:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among the Borrower, the Lenders party thereto and the Administrative Agent, the Lenders have extended a Commitment to make Loans to the Borrower; and

WHEREAS, as a condition precedent to the making of the Loans and as an inducement for the Lenders to make the Loans, in each case, under the Credit Agreement, each Grantor is required to execute and deliver this Security Agreement;

WHEREAS, it is required under the terms of the Credit Agreement that the Grantors shall have granted, pledged and assigned the security interests and undertaken the obligations contemplated by this Security Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Grantor agrees, for the benefit of the Secured Parties, as follows:

ARTICLE I DEFINITIONS

SECTION 1.1. <u>Certain Terms</u>. The following terms (whether or not underscored) when used in this Security Agreement, including its preamble and recitals, shall have the following meanings (such definitions to be equally applicable to the singular and plural forms thereof):

"Administrative Agent" is defined in the preamble.

"Bioprojet Agreements" means the Key Contracts listed in clauses (a) through (b) of the definition thereof as of the date hereof, including any replacement thereof.

"Borrower" is defined in the preamble.

"Collateral" is defined in Section 2.1.

"Collateral Accounts" is defined in Section 4.3(b).

"Computer Hardware and Software Collateral" means (a) all of the Grantors' owned computer and other electronic data processing hardware, integrated computer systems, central processing units, memory units, display terminals, printers, features, computer elements, card readers, tape drives, hard and soft disk drives, cables, electrical supply hardware, generators, power equalizers, accessories and all peripheral devices and other related computer hardware, including all operating system software, utilities and application programs in whatsoever form; (b) all software programs (including both source code, object code and all related applications and data files) designed for use on the computers and electronic data processing hardware described in clause (a) above; (c) all firmware associated therewith; (d) all documentation (including flow charts, logic diagrams, manuals, guides, specifications, training materials, charts and pseudo codes) with respect to such hardware, software and firmware described in the preceding clauses (a) through (c); and (e) all rights with respect to all of the foregoing, including copyrights, licenses, options, warranties, service contracts, program services, test rights, maintenance rights, support rights, improvement rights, renewal rights and indemnifications and any substitutions, replacements, improvements, error corrections, updates, additions or model conversions of any of the foregoing.

"Control Agreement" means an authenticated record in form and substance reasonably satisfactory to the Administrative Agent, that provides for the Administrative Agent to have "control" (as defined in the UCC) over certain Collateral.

"Copyright Collateral" means all Copyrights, including: (a) the Copyrights referred to in Item A of Schedule V, and registrations and recordings thereof and all applications for registration thereof, whether pending or in preparation; (b) all Copyright licenses, including each material Copyright license referred to in Item B of Schedule V; (c) the right to sue for past, present and future infringements of any of the foregoing, all rights corresponding thereto, all extensions and renewals of any thereof; and (d) all Proceeds of the foregoing, including licenses, royalties, income, payments, claims, damages and Proceeds of suit, which are owned or licensed by the Grantors.

"Credit Agreement" is defined in the first recital.

"<u>Distributions</u>" means all dividends paid on Capital Securities, liquidating dividends paid on Capital Securities, shares (or other designations) of Capital Securities resulting from (or in connection with the exercise of) stock splits, reclassifications, warrants, options, non-cash dividends, mergers, consolidations, and all other distributions (whether similar or dissimilar to the foregoing) on or with respect to any Capital Securities constituting Collateral.

"Financing Statements" is defined in Section 3.7(b).

"General Intangibles" means all "general intangibles" and all "payment intangibles", each as defined in the UCC and shall include all interest rate or currency protection or hedging arrangements, all tax refunds, all licenses, permits, concessions and authorizations and all Intellectual Property Collateral (in each case, regardless of whether characterized as general intangibles under the UCC).

"Grantor" and "Grantors" are defined in the preamble.

"Holdings" is defined in the preamble.

"Intellectual Property Collateral" means, collectively, the Computer Hardware and Software Collateral, the Copyright Collateral, the Patent Collateral, the Trademark Collateral and the Trade Secrets Collateral.

"Intercompany Note" means any promissory note evidencing loans made by any Grantor to any other Grantor.

"Investment Property" means, collectively, (a) all "investment property" as such term is defined in Section 9-102(a)(49) of the UCC and (b) whether or not constituting "investment property" as so defined, all Pledged Notes.

"Motor Vehicles" means motor vehicles, tractors, trailers and other like property, if the title thereto is governed by a certificate of title or ownership.

"Patent Collateral" means:

- (a) all of the Patents, including all Patent applications in preparation for filing and each Patent and Patent application referred to in Item A of Schedule III;
- (b) all Patent licenses, and other agreements providing any Grantor with the right to use any items of the type referred to in <u>clause (a)</u> above, including each Patent license referred to in <u>Item B</u> of <u>Schedule III</u> (excluding any licenses to any Grantor for commercially available off-the-shelf software); and
- (c) all Proceeds of, and rights associated with, the foregoing (including licenses, royalties income, payments, claims, damages and Proceeds of infringement suits) and the right to sue third parties for past, present or future infringements of any Patent and for breach or enforcement of any patent license.

"Permitted Liens" means all Liens permitted by Section 8.3 of the Credit Agreement.

"<u>Pledged Notes</u>" means all promissory notes listed on <u>Item J</u> of <u>Schedule II</u> (as such schedule may be amended or supplemented from time to time), all Intercompany Notes at any time issued to any Grantor and all other promissory notes issued to or held by any Grantor.

"Secured Parties" means, collectively, the Administrative Agent and the Lenders and "Secured Party" means any one of them.

"Securities Act" is defined in Section 6.2(a).

"Security Agreement" is defined in the preamble.

"Trade Secrets" is defined in the definition of "Trade Secrets Collateral."

"Trade Secrets Collateral" means (a) all of the Grantors' common Law and statutory trade secrets and all other confidential and proprietary information, and all know-how obtained by or used in the business of any Grantor (all of the foregoing being collectively called a "Trade Secret"), whether or not such Trade Secret has been reduced to a writing or other tangible form, including all documents and things embodying, incorporating or referring in any way to such Trade Secret; (b) all Trade Secret licenses, including each Trade Secret license referred to in Schedule VI (excluding any licenses to any Grantor for commercially available off-the-shelf software); and (c) including the right to sue for and to enjoin and to collect damages for the actual or threatened misappropriation of any Trade Secret and for the breach or enforcement of any such Trade Secret license.

"Trademark Collateral" means:

- (a) (i) all of the Grantors' Trademarks and all goodwill of the business associated therewith, now existing or hereafter adopted or acquired including those referred to in Item A of Schedule IV, whether currently in use or not, all registrations and recordings thereof and all applications in connection therewith, whether pending or in preparation for filing, including registrations, recordings and applications in the United States Patent and Trademark (the "USPTO") or in any office or agency of the United States of America, or any state thereof or any other country or political subdivision thereof or otherwise, and all common-law rights relating to the foregoing, and (ii) the right to obtain all reissues, extensions or renewals of the foregoing;
- (b) all Trademark licenses for the grant by or to any Grantors of any right to use any Trademark, including each Trademark license referred to in <u>Item B</u> of <u>Schedule IV</u> (excluding any licenses to any Grantor for commercially available off-the-shelf software);
- (c) the right to sue third parties for past, present and future infringements of any Trademark Collateral described in <u>clause (a)</u> and, to the extent applicable, <u>clause (b)</u>; and
- (d) all Proceeds of, and rights associated with, the foregoing, including any claim by any Grantor against third parties for past, present or future infringement or dilution of any Trademark, Trademark registration or Trademark license, or for any injury to the goodwill associated with the use of any such Trademark or for breach or enforcement of any Trademark license and all rights corresponding thereto throughout the world.
- SECTION 1.2. <u>Credit Agreement Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Security Agreement, including its preamble and recitals, have the meanings provided in the Credit Agreement.
- SECTION 1.3. <u>UCC Definitions</u>. When used herein the terms "Account", "Certificated Securities", "Chattel Paper", "Commercial Tort Claim", "Commodity Account", "Commodity Contract", "Deposit Account", "Document", "Electronic Chattel Paper", "Equipment", "Goods", "Instrument", "Inventory", "Letter of Credit Rights", "Payment Intangibles", "Proceeds", "Promissory Notes", "Securities Account", "Security Entitlement", "Supporting Obligations" and "Uncertificated Securities" have the meaning provided in Article 9, as applicable, of the UCC. "Letters of Credit" has the meaning provided in Section 5-102 of the UCC.

ARTICLE II SECURITY INTEREST

- SECTION 2.1. <u>Grant of Security Interest</u>. Each Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of such Grantor's right, title and interest in and to the following property, whether now or hereafter existing, owned or acquired by such Grantor, and wherever located (collectively, the "<u>Collateral</u>"):
 - (a) Accounts;
 - (b) Chattel Paper;
- (c) Commercial Tort Claims, including those listed on <u>Item I</u> of <u>Schedule II</u> (as such schedule may be amended or supplemented from time to time);
 - (d) Deposit Accounts;
 - (e) Documents;
 - (f) General Intangibles;
 - (g) Goods (including Goods held on consignment with third parties);
 - (h) Instruments;
 - (i) Investment Property;
 - (j) Letter of Credit Rights and Letters of Credit;
 - (k) Supporting Obligations;
- (l) all books, records, writings, databases, information and other property relating to, used or useful in connection with, evidencing, embodying, incorporating or referring to, any of the foregoing in this <u>Section 2.1</u>;
- (m) all Proceeds of any of the foregoing and, to the extent not otherwise included, (i) all payments under insurance (whether or not the Administrative Agent is the loss payee thereof) in respect of Collateral and (ii) all tort claims; and
 - (n) all other property and rights of every kind and description and interests therein.

Notwithstanding anything to the contrary, the term "Collateral" shall not include:

(i) any General Intangibles or other rights, in each case arising under any contracts, instruments, lease, licenses or other documents as to which the grant of a security interest would (A) constitute or result in a violation, breach, termination, default or invalidity thereunder or thereof in favor of a third party, unless and until any required consents shall have been obtained or (B) give any other party to such contract, instrument, license or other document the right to terminate its obligations thereunder, including any Key Contract or Material Agreement to the extent described in this clause (i):

- (ii) Trademark applications filed in the USPTO on the basis of such Grantor's "intent to use" such trademark, unless and until acceptable evidence of use of the Trademark has been filed with the USPTO pursuant to Section 1(c) or Section 1(d) of the Lanham Act (15 U.S.C. 1051, et seq.), to the extent that granting a Lien in such Trademark application prior to such filing would adversely affect the enforceability or validity of such Trademark application;
- (iii) any asset, the granting of a security interest in which would be void, materially restricted or illegal under any applicable Law (including, without limitation, any requirement made under applicable Law to obtain the consent or approval of any Governmental Authority), or pursuant thereto would result in, or permit the termination of, such asset; or
- (iv) any asset subject to a Permitted Lien (other than Liens in favor of the Secured Parties) securing obligations permitted under the Credit Agreement to the extent that the grant of other Liens on such asset (A) would result in a breach, termination, invalidity or violation of, or constitute a default under, the agreement or instrument governing such Permitted Lien (or the transaction or obligations secured thereby), (B) would result in the loss of use of such asset or (C) would permit the holder of such Permitted Lien to terminate the Grantor's use of such asset;
 - (v) the Excluded Accounts, as that term is defined in Section 7.13 of the Credit Agreement;
- (vi) any assets with respect to which the Administrative Agent determines, in its reasonable discretion, that the cost of obtaining a security interest therein, or Lien thereon exceed the practical benefits to the Secured Parties of the security afforded thereby;
 - (vii) any leasehold or subleasehold interests in any real property; and
 - (viii) any Motor Vehicles.

<u>provided</u> that the property described in each of <u>clauses (i)</u>, <u>(iii)</u> and <u>(iv)</u> above shall only be excluded from the term "Collateral" to the extent the conditions stated in such clauses are not rendered ineffective pursuant to Sections 9-406, 9-407, 9-408 or 9-409 of the UCC or any other applicable Law;

<u>provided further</u> that the property described in each of <u>clauses (i)</u> through (<u>vii)</u> above shall not include any Proceeds, products, substitutions or replacements thereof (unless such Proceeds, products, substitutions or replacements would otherwise constitute property described in any of <u>clauses</u> (<u>i)</u> through (<u>vii)</u> above).

SECTION 2.2. <u>Security for Obligations</u>. This Security Agreement and the Collateral in which the Administrative Agent, for the benefit of the Secured Parties, is granted a security interest hereunder by the Grantors to secure the payment and performance of all of the Obligations.

SECTION 2.3. Grantors Remain Liable. Anything herein to the contrary notwithstanding:

- (a) the Grantors will remain liable under the contracts and agreements included in the Collateral to the extent set forth therein, and will perform all of their duties and obligations under such contracts and agreements to the same extent as if this Security Agreement had not been executed;
- (b) the exercise by any Secured Party of any of its rights hereunder will not release any Grantor from any of its duties or obligations under any such contracts or agreements included in the Collateral; and
- (c) the Secured Parties will not have any obligation or liability under any contracts or agreements included in the Collateral by reason of this Security Agreement, nor will the Secured Parties be obligated to perform any of the obligations or duties of any Grantor thereunder or to take any action to collect or enforce any claim for payment assigned hereunder.
- SECTION 2.4. <u>Distributions on Capital Securities; Payments on Pledged Notes</u>. In the event that any (a) Distribution with respect to any Capital Securities or (b) payment with respect to any Pledged Notes, in each case pledged hereunder, is not prohibited under Section 8.6 of the Credit Agreement, such Distribution or payment may be paid directly to the applicable Grantor. If any Distribution or payment is made in contravention of Sections 8.5 or 8.6 of the Credit Agreement, such Grantor shall hold the same segregated and in trust for the Administrative Agent, for the benefit of the Secured Parties, until paid to the Administrative Agent in accordance with <u>Section 4.1.5</u>.
- SECTION 2.5. <u>Security Interest Absolute, Etc.</u>. This Security Agreement shall in all respects be a continuing, absolute, unconditional and irrevocable grant of security interest and shall remain in full force and effect, in each case, until the Termination Date. All rights of the Secured Parties and the security interests granted to the Administrative Agent, for the benefit of the Secured Parties, hereunder, and all obligations of the Grantors hereunder, shall, to the fullest extent permitted by applicable Law, in each case, be absolute, unconditional and irrevocable irrespective of:
 - (a) any lack of validity, legality or enforceability of any Loan Document (other than this Security Agreement);
- (b) the failure of any Secured Party (i) to assert any claim or demand or to enforce any right or remedy against the Borrower, Holdings or any of the Subsidiaries or any other Person (including any other Grantor) under the provisions of any Loan Document or otherwise, or
 - (i) to exercise any right or remedy against any other guarantor (including any other Grantor) of, or Collateral securing, any Obligations;
- (c) any change in the time, manner or place of payment of, or in any other term of, all or any part of the Obligations, or any other extension, compromise or renewal of any Obligations;

- (d) any reduction, limitation, impairment or termination of any Obligations for any reason, including any claim of waiver, release, surrender, alteration or compromise and shall not be subject to (and each Grantor hereby waives, until payment of all Obligations, any right to or claim of) any defense or setoff, counterclaim, recoupment or termination whatsoever by reason of the invalidity, illegality, nongenuineness, irregularity, compromise, unenforceability of, or any other event or occurrence affecting, any Obligations or otherwise;
- (e) any amendment to, rescission, waiver, or other modification of, or any consent to or departure from, any of the terms of any Loan Document;
- (f) any addition, exchange or release of any Collateral or of any Person that is (or will become) a Grantor (including the Grantors hereunder), or any surrender or non-perfection of any Collateral, or any amendment to or waiver or release or addition to, or consent to or departure from, any other guaranty held by the Administrative Agent, for the benefit of the Secured Parties, securing any of the Obligations; or
- (g) any other circumstance which might otherwise constitute a defense available to, or a legal or equitable discharge of the Borrower, Holdings or any of the Subsidiaries, any surety or any guarantor.
- SECTION 2.6. <u>Postponement of Subrogation</u>. Each Grantor agrees that it will not exercise any rights against another Grantor which it may acquire by way of rights of subrogation under any Loan Document to which it is a party until following the Termination Date. No Grantor shall seek or be entitled to seek any contribution or reimbursement from the Borrower, Holdings or any other Grantor, in respect of any payment made under any Loan Document or otherwise, until following the Termination Date. Any amount paid to any Grantor on account of any such subrogation rights prior to the Termination Date shall be held in trust for the benefit of the Secured Parties and shall immediately be paid and turned over to the Administrative Agent, for the benefit of the Secured Parties, in the exact form received by such Grantor (duly endorsed in favor of the Administrative Agent, if required), to be credited and applied against the Obligations, whether matured or unmatured, in accordance with <u>Section 6.1(b)</u>; <u>provided</u> that if such Grantor has made payment to the Administrative Agent of all or any part of the Obligations and the Termination Date has occurred, then at such Grantor's request, the Administrative Agent will, at the expense of such Grantor, execute and deliver to such Grantor appropriate documents (without recourse and without representation or warranty) necessary to evidence the transfer by subrogation to such Grantor of an interest in the Obligations resulting from such payment. In furtherance of the foregoing, at all times prior to the Termination Date, such Grantor shall refrain from taking any action or commencing any proceeding against the Borrower, Holdings or any other Grantor (or their successors or assigns, whether in connection with a bankruptcy proceeding or otherwise) to recover any amounts in respect of payments made under this Security Agreement to the Administrative Agent or any other Secured Party.

ARTICLE III REPRESENTATIONS AND WARRANTIES

In order to induce the Secured Parties to enter into the Credit Agreement and make the Loans thereunder, the Grantors represent and warrant to the Administrative Agent, for the benefit of the Secured Parties, as set forth below.

SECTION 3.1. As to Capital Securities of the Subsidiaries, Investment Property.

- (a) With respect to any Subsidiary of any Grantor that is:
- (i) a corporation, business trust, joint stock company or similar Person, all Capital Securities issued by such Subsidiary are duly authorized and validly issued, fully paid and non-assessable, and represented by a certificate or certificates; and
- (ii) a partnership or limited liability company, no Capital Securities issued by such Subsidiary (including the Borrower) (A) is dealt in or traded on securities exchanges or in securities markets, (B) expressly provides that such Capital Securities is a security governed by Article 8 of the UCC or (C) is held in a Securities Account, except, with respect to this <u>clause (a)(ii)</u>, Capital Securities (x) for which the Administrative Agent is the registered owner or (y) with respect to which the issuer has agreed in an authenticated record with such Grantor and the Administrative Agent to comply with any instructions of the Administrative Agent without the consent of such Grantor.
- (b) Each Grantor has delivered all Certificated Securities constituting Collateral held by such Grantor in a Subsidiary (including the Borrower) on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement) to the Administrative Agent, together with duly executed undated blank stock powers, or other equivalent instruments of transfer acceptable to the Administrative Agent.

(c) [Reserved]

- (d) The percentage of the issued and outstanding Capital Securities of each Subsidiary (including the Borrower) pledged on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement) by each Grantor hereunder is as set forth on Schedule I. All shares of such Capital Securities have been duly and validly issued and are fully paid and non-assessable (in the case of any Capital Securities issued by a corporation) or duly issued and outstanding (in the case of any Capital Securities in any partnership or limited liability company).
- (e) Each of the Intercompany Notes constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting creditors' rights generally, general equitable principle s (whether considered in a proceeding in equity or at Law) and an implied covenant of good faith and fair dealing.

- SECTION 3.2. <u>Grantor Name, Location, Etc.</u> In each case as of the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement):
- (a) (i) The jurisdiction in which each Grantor is located for purposes of Sections 9-301 and 9-307 of the UCC and (ii) the address of each Grantor's executive office and principal place of business is set forth in <u>Item A</u> of <u>Schedule II</u>.
 - (b) The Grantors do not have any trade names other than those set forth in <u>Item C</u> of <u>Schedule II</u> hereto.
- (c) During the twelve (12) months preceding the date hereof (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, preceding the date such Grantor becomes a party to this Security Agreement), no Grantor has been known by any legal name different from the one set forth on the signature page hereto, nor has such Grantor been the subject of any merger or other corporate reorganization, except as set forth in Item D of Schedule II hereto.
- (d) Each Grantor's federal taxpayer identification number (or foreign equivalent) is (and, during the twelve (12) months preceding the date hereof (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, preceding the date such Grantor becomes a party to this Security Agreement), such Grantor has not had a federal taxpayer identification number (or equivalent) different from that) set forth in <u>Item E</u> of <u>Schedule II</u> hereto.
 - (e) No Grantor is a party to any federal, state or local government contract except as set forth in <u>Item F</u> of <u>Schedule II</u> hereto.
- (f) No Grantor maintains any Deposit Accounts, Securities Accounts or Commodity Accounts with any Person, in each case, except as set forth on $\underline{\text{Item } G}$ of $\underline{\text{Schedule II}}$.
 - (g) No Grantor is the beneficiary of any Letters of Credit in excess of \$500,000, except as set forth on Item H of Schedule II.
 - (h) No Grantor has Commercial Tort Claims in favor of such Grantor in excess of \$500,000 except as set forth on Item I of Schedule II.
- (i) The name set forth on the signature page attached hereto (or the signature page of the supplement hereto by which such Grantor has become a party to this Security Agreement, as applicable) is the true and correct legal name (as defined in the UCC) of each Grantor.
- SECTION 3.3. Ownership, No Liens, Etc. Each Grantor owns its Collateral free and clear of any Lien, except for (a) any security interest created by this Security Agreement and (b) Permitted Liens. No effective UCC financing statement or other filing similar in effect covering all or any part of the Collateral is on file in any recording office, except those filed in favor of the Administrative Agent relating to this Security Agreement, Permitted Liens or as to which a duly authorized termination statement relating to such UCC financing statement or other instrument has

been delivered to the Administrative Agent on the Closing Date. No Grantor has granted a Lien (other than non-consensual Permitted Liens and Permitted Liens described in clauses (a) and (k) of Section 8.3 of the Credit Agreement) in any Bioprojet Agreement to any Person, other than the Secured Parties to the extent contemplated under this Agreement.

SECTION 3.4. Possession of Inventory, Control, Etc.

- (a) Each Grantor has, and agrees that it will maintain, exclusive possession of its Documents, Instruments, Promissory Notes, Goods, Equipment and Inventory, other than (i) Equipment or Inventory that is in transit in the ordinary course of business, (ii) Equipment or Inventory that in the ordinary course of business is in the possession or control of a warehouseman, bailee agent or other Person (other than a Person controlled by or under common control with such Grantor), with respect to any such assets with an aggregate value in excess of \$2,000,000, that has been notified of the security interest created in favor of the Administrative Agent, for the benefit of the Secured Parties, pursuant to this Security Agreement and with respect to which such Grantor has exercised commercially reasonable efforts to have authenticated a record acknowledging that such warehouseman, bailee agent or other Person holds possession of such Collateral for the benefit of the Secured Parties and waives any Lien held by it against such Collateral, (iii) Inventory that is in the possession of any Person in connection with a conditional sale, title retention, consignment or similar arrangements for sale of goods or products in the ordinary course of business and (iv) any Documents, Instruments, Promissory Notes, Goods, Equipment and Inventory that have been delivered to the Administrative Agent.
- (b) Each Grantor is the sole entitlement holder of its Deposit Accounts, and no other Person (other than the Administrative Agent pursuant to this Security Agreement or any other Person with respect to Permitted Liens) has control or possession of, or any other interest in, any of its Deposit Accounts or any other securities or property credited thereto, in each case, except as otherwise expressly permitted under the Credit Agreement.
- SECTION 3.5. <u>Negotiable Instruments and Chattel Paper</u>. Each Grantor has delivered to the Administrative Agent possession of all originals of all Instruments, Promissory Notes and tangible Chattel Paper (other than any Intercompany Note, any Instrument, Promissory Note or tangible Chattel Paper held in a Securities Account or any Instrument, Promissory Note or tangible Chattel Paper not exceeding \$500,000 in principal amount individually or \$1,000,000 in principal amount in the aggregate) held by such Grantor on the Closing Date (or, solely with respect to a Grantor that becomes a party to this Security Agreement after the Closing Date, on the date such Grantor becomes a party to this Security Agreement).
- SECTION 3.6. <u>Intellectual Property Collateral</u>. Except as disclosed on <u>Schedules III</u> through <u>VI</u>, with respect to any Intellectual Property Collateral:
- (a) any material Intellectual Property Collateral owned by any Grantor is, to the knowledge of such Grantor, valid, subsisting, unexpired and enforceable and has not been abandoned or adjudged invalid or unenforceable, in whole or in part;
- (b) such Grantor is the sole and exclusive owner of the entire and unencumbered right, title and interest in and to all Intellectual Property Collateral owned by such Grantor and to the knowledge of such Grantor, no claim has been made that the use of such Intellectual Property Collateral by such Grantor does or may, conflict with, infringe, misappropriate, dilute, misuse or otherwise violate in any material respect, any of the rights of any third party;

- (c) such Grantor has made all necessary filings and recordations to protect its interest in any Intellectual Property Collateral owned by such Grantor to the extent such filing or recordation is necessary for the conduct of the business substantially in the manner presently conducted, including recordations of all of its interests in the Patent Collateral and Trademark Collateral in the USPTO or foreign equivalent, and its claims to the Copyright Collateral in the United States Copyright Office (the "<u>USCO</u>") or foreign equivalent, and, to the extent necessary, has used proper statutory notice in connection with its use of any material Patent, Trademark and Copyright in any of such Intellectual Property Collateral;
- (d) such Grantor has taken all reasonable steps to safeguard its Trade Secrets and to its knowledge (i) none of the Trade Secrets of such Grantor has been used, divulged, disclosed or appropriated for the benefit of any other Person other than a Grantor; (ii) no employee, independent contractor or agent of such Grantor has misappropriated any Trade Secrets of any other Person in the course of the performance of his or her duties as an employee, independent contractor or agent of such Grantor is in default or breach of any material term of any employment agreement, non-disclosure agreement, assignment of inventions agreement or similar agreement or contract relating in any material way to the protection, ownership, development, use or transfer of such Grantor's Intellectual Property Collateral;
- (e) to such Grantor's knowledge, no third party is infringing upon any Intellectual Property owned or used by such Grantor in any material respect, or any of its respective licensees in any material respect;
- (f) no written settlement or consents, covenants not to sue, nonassertion assurances, or releases have been entered into by such Grantor or to which such Grantor is bound that adversely affects its rights to own or use any Intellectual Property in any material respect;
- (g) such Grantor has not granted a Lien in any Intellectual Property Collateral owned by such Grantor that has not been terminated or released except Permitted Liens;
- (h) such Grantor has executed and delivered to the Administrative Agent Intellectual Property Collateral security agreements for all applications and registrations for all Copyrights, Patents and Trademarks owned by such Grantor;
- (i) such Grantor uses commercially reasonable efforts designed to ensure the quality of the manufacture, distribution and sale of all products sold by the Grantor and in the provision of all services rendered under or in connection with all Trademarks and has taken all commercially reasonable actions necessary to ensure that all licensees of the Trademarks owned by such Grantor use such adequate standards of quality;

- (j) the consummation of the transactions contemplated by the Credit Agreement and this Security Agreement will not result in the termination or material impairment of any material portion of the Intellectual Property Collateral; and
- (k) to such Grantor's knowledge, such Grantor owns or is entitled to use by license, lease or other agreement, all Patents, Trademarks, Trade Secrets, Copyrights, mask works, licenses, technology, know-how, processes and rights with respect to any of the foregoing as necessary to conduct the business and operations of such Grantor substantially in the manner presently conducted.

SECTION 3.7. Validity, Etc.

- (a) This Security Agreement creates a valid security interest in the Collateral securing the payment of the Obligations to the extent such security interest may be created pursuant to Article 9 of the UCC.
- (b) Upon the filing of a UCC-1 financing statement naming the applicable Grantor as debtor, the Administrative Agent as secured party and listing all personal property as the collateral (collectively, the "<u>Financing Statements</u>") in the jurisdiction of organization of each Grantor set forth in <u>Item A</u> of <u>Schedule II</u> with the appropriate agencies therefor, the security interests created under this Security Agreement shall constitute a perfected security interest in the Collateral described on such Financing Statements in favor of the Administrative Agent to the extent that a security interest therein may be perfected by filing a financing statement pursuant to the relevant UCC, prior to all other Liens, except for Permitted Liens.
- SECTION 3.8. <u>Authorization, Approval, Etc.</u> Except as have been obtained or made and are in full force and effect or except with respect to the Financing Statements or, with respect to Intellectual Property Collateral, the recordation of any agreements with the USPTO or the USCO, no authorization, approval or other action by, and no notice to or filing with, any Governmental Authority is required for the grant by the Grantors of the security interest granted hereby or for the execution, delivery and performance of this Security Agreement by the Grantors.
- SECTION 3.9. <u>Best Interests</u>. It is in the best interests of each Grantor (other than the Borrower) to execute this Security Agreement inasmuch as such Grantor will, as a result of being an Affiliate of the Borrower, derive substantial direct and indirect benefits from the Loans made to the Borrower by the Lenders pursuant to the Credit Agreement, and each Grantor agrees that the Lenders are relying on this representation in agreeing to make such Loans pursuant to the Credit Agreement to the Borrower.

ARTICLE IV COVENANTS

Each Grantor covenants and agrees that, until the Termination Date, such Grantor will perform, comply with and be bound by the obligations set forth below.

SECTION 4.1. As to Investment Property, Etc.

SECTION 4.1.1 Capital Securities of Subsidiaries. No Grantor will allow any of its Subsidiaries (including the Borrower):

- (a) that is a corporation, business trust, joint stock company or similar Person, to issue Uncertificated Securities;
- (b) that is a partnership or limited liability company, to (i) issue Capital Securities that are to be dealt in or traded on securities exchanges or in securities markets, (ii) expressly provide in its Organic Documents that its Capital Securities are securities governed by Article 8 of the UCC or (iii) place such Subsidiary's Capital Securities in a Securities Account; and
- (c) to issue Capital Securities in addition to or in substitution for the Capital Securities pledged hereunder, except to such Grantor (and such Capital Securities are immediately pledged and delivered to the Administrative Agent pursuant to the terms of this Security Agreement).

SECTION 4.1.2 <u>Investment Property (other than Certificated Securities)</u>.

- (a) Upon (or such later date as Administrative Agent may agree to) a Grantor's acquisition or creation of any Deposit Accounts or Securities Accounts (other than Excluded Accounts), such Grantor will cause the bank or securities intermediary maintaining such deposit Accounts or Securities Account to execute a Control Agreement relating thereto.
- (b) With respect to any Uncertificated Securities (other than Uncertificated Securities credited to a Securities Account) issued by a Person other than the Borrower or a Subsidiary constituting Investment Property owned or held by any Grantor, such Grantor will, upon written request from Administrative Agent, cause the issuer of such securities to either (i) register the Administrative Agent as the registered owner thereof on the books and records of the issuer or (ii) execute a Control Agreement relating to such Investment Property pursuant to which the issuer agrees to comply with the Administrative Agent's instructions with respect to such Uncertificated Securities without further consent by such Grantor. With respect to Uncertificated Securities of the Borrower or any Subsidiary, the Grantor issuer of such Securities hereby agrees to comply with the Administrative Agent's instructions with respect to such Uncertificated Securities without further consent by such Grantor, and the Administrative Agent hereby agrees not to give such instructions unless an Event of Default has occurred and is continuing.
- (c) Except as otherwise permitted under the Credit Agreement (including Permitted Liens), no Grantor shall cause or permit any Person other than Administrative Agent or the Secured Parties to have "control" (as defined in Section 9-104, 9-105, 9-106 or 9-107 of the UCC) of any Investment Property constituting part of the Collateral.
- SECTION 4.1.3 <u>Certificated Securities (Stock Powers)</u>. Each Grantor agrees that all Certificated Securities constituting Collateral, including the Capital Securities delivered by such Grantor pursuant to this Security Agreement, will be accompanied by duly executed undated blank stock powers, or other equivalent instruments of transfer reasonably acceptable to the Administrative Agent.

SECTION 4.1.4 <u>Continuous Pledge</u>. Each Grantor will (subject to the terms of the Credit Agreement) deliver to the Administrative Agent all Investment Property and all Payment Intangibles that constitute Collateral to the extent that such Investment Property or Payment Intangibles are evidenced by a Document, Instrument, Promissory Note or Chattel Paper (other than any Intercompany Notes, any Document, Instrument, Promissory Note or Chattel Paper held in a Securities Account or any Document, Instrument, Promissory Note or Chattel Paper not exceeding \$500,000 in principal amount individually or \$1,000,000 in principal amount in the aggregate).

SECTION 4.1.5 <u>Voting Rights, Dividends, Etc.</u> Each Grantor agrees:

- (a) upon receipt of notice of the occurrence and continuance of an Event of Default from the Administrative Agent and request therefor by the Administrative Agent, so long as such Event of Default shall continue, to deliver (properly endorsed where required hereby or requested by the Administrative Agent) to the Administrative Agent all dividends and Distributions with respect to Investment Property constituting Collateral; all interest, principal, other cash payments on Payment Intangibles; and all Proceeds of the Collateral, in each case thereafter received by such Grantor, all of which shall be held by the Administrative Agent as additional Collateral, except for payments made in accordance with Section 8.6 of the Credit Agreement; and
- (b) immediately upon the occurrence and during the continuance of an Event of Default and so long as the Administrative Agent has notified such Grantor of the Administrative Agent's intention to exercise its voting power under this <u>clause (b)</u>,
- (i) with respect to Collateral consisting of general partner interests or limited liability company interests, to promptly modify its Organic Documents to admit the Administrative Agent as a general partner or member, as applicable;
- (ii) that the Administrative Agent may exercise (to the exclusion of such Grantor) the voting power and all other incidental rights of ownership with respect to any Investment Property constituting Collateral, and such Grantor hereby grants the Administrative Agent an irrevocable proxy, exercisable under such circumstances, to vote such Investment Property; and
- (iii) to promptly deliver to the Administrative Agent such additional proxies and other documents as are reasonably requested by Administrative Agent which are necessary to allow the Administrative Agent to exercise such voting power.

All dividends, Distributions, interest, principal, cash payments, Payment Intangibles and Proceeds constituting Collateral that may at any time and from time to time be held by such Grantor, but which such Grantor is then obligated to deliver to the Administrative Agent, shall, until delivery to the Administrative Agent, be held by such Grantor separate and apart from its other property in trust for the Administrative Agent. The Administrative Agent agrees that unless an Event of Default shall have occurred and be continuing and the Administrative Agent shall have given the notice referred to in this <u>clause (b)</u>, such Grantor will have the exclusive voting power with respect to any Investment Property and the Administrative Agent will, upon the written request of such

Grantor, promptly deliver such proxies and other documents, if any, as shall be reasonably requested by such Grantor which are necessary to allow such Grantor to exercise that voting power; <u>provided</u> that no vote shall be cast, or consent, waiver or ratification given, or action taken by such Grantor that would impair any such Collateral or be inconsistent with or violate any provision of any Loan Document.

SECTION 4.2. <u>Change of Name, Etc.</u> No Grantor will change its name or place of incorporation or organization or federal taxpayer identification number except as otherwise permitted by the Credit Agreement.

SECTION 4.3. As to Accounts.

- (a) Each Grantor shall have the right to collect all Accounts so long as no Event of Default shall have occurred and be continuing.
- (b) Upon (i) the occurrence and continuance of an Event of Default and (ii) the delivery of notice by the Administrative Agent to each Grantor, all Proceeds of Collateral received by such Grantor shall be delivered in kind to the Administrative Agent and, until delivered to Administrative Agent, shall be deposited in a Deposit Account of such Grantor maintained with the Administrative Agent or that otherwise is a Controlled Account (such Deposit Accounts or Controlled Accounts, collectively, the "Collateral Accounts"), and such Grantor shall not commingle any such Proceeds and shall hold, separate and apart from all other property, all such Proceeds in express trust for the benefit of the Administrative Agent until delivery thereof is made to the Administrative Agent.
- (c) Following the delivery of notice pursuant to <u>clause (b)(ii)</u> above, the Administrative Agent shall have the right to apply any amount in the Collateral Accounts to the payment of any Obligations which are then due and payable in accordance with Section 9.4 of the Credit Agreement.

SECTION 4.4. As to Grantors' Use of Collateral.

- (a) Subject to <u>clause (b)</u> below, each Grantor: (i) may in the ordinary course of its business, at its own expense, sell, lease or furnish under contracts of service any of the Inventory normally held by such Grantor for such purpose, and use and consume, in the ordinary course of its business, any raw materials, work in process or materials normally held by such Grantor for such purpose, (ii) will, at its own expense, endeavor to collect, as and when due, all amounts due with respect to any of the Collateral, including the taking of such action with respect to such collection as the Administrative Agent may reasonably request following the occurrence and during the continuance of an Event of Default or, in the absence of such request, as such Grantor may deem advisable, (iii) may grant, in the ordinary course of business, to any party obligated on any of the Collateral, any rebate, refund or allowance to which such party may be lawfully entitle d, and may accept, in connection therewith, the return of Goods, the sale or lease of which shall have given rise to such Collateral, or (iv) may make Dispositions permitted under the Credit Agreement.
- (b) At any time following the occurrence and during the continuance of an Event of Default, whether before or after the maturity of any of the Obligations until the

Termination Date, the Administrative Agent may: (i) revoke any or all of the rights of each Grantor set forth in <u>clause (a)</u> above, (ii) notify any parties obligated on any of the Collateral to make payment to the Administrative Agent of any amounts due or to become due thereunder and (iii) enforce collection of any of the Collateral by suit or otherwise and surrender, release or exchange all or any part thereof, or compromise or extend or renew for any period (whether or not longer than the original period) any indebtedness thereunder or evidenced thereby.

- (c) Upon the request of the Administrative Agent following the occurrence and during the continuance of an Event of Default, each Grantor will, at its own expense, notify any parties obligated on any of the Collateral to make payment to the Administrative Agent of any amounts due or to become due thereunder.
- (d) At any time following the occurrence and during the continuance of an Event of Default, the Administrative Agent may endorse, in the name of such Grantor, any item, howsoever received by the Administrative Agent, representing any payment on or other Proceeds of any of the Collateral.
- (e) No Grantor may grant a Lien (other than non-consensual Permitted Liens and Permitted Liens described in clauses (a) and (k) of Section 8.3 of the Credit Agreement) on any Bioprojet Agreement to any Person, other than the Secured Parties.
- SECTION 4.5. <u>As to Intellectual Property Collateral</u>. Each Grantor covenants and agrees to comply with the following provisions as such provisions relate to any Intellectual Property Collateral material to the operations or business of such Grantor:
- (a) such Grantor will not (i) do or fail to perform any act whereby any of the Patent Collateral may lapse or become abandoned or dedicated to the public or unenforceable, (ii) authorize any of its licensees to (A) fail to continue to use any of the Trademark Collateral in order to maintain all of the Trademark Collateral in full force free from any claim of abandonment for non-use, (B) fail to maintain the quality of products and services offered under all of the Trademark Collateral at a level substantially consistent with the quality of products and services offered under such Trademark as of the date hereof, (C) [reserved], (D) [reserved], (E) [reserved] or (F) do or permit any act or knowingly omit to do any act whereby any of the Trademark Collateral may become invalid or unenforceable or (iii) do or permit any act or knowingly omit to do any act whereby any of the Copyright Collateral or any of the Trade Secrets Collateral may lapse or become invalid or unenforceable or placed in the public domain except upon expiration of the end of an unrenewable term of a registration thereof, unless, in the case of any of the foregoing requirements in clauses (i), (ii) and (iii), such Grantor reasonably and in good faith determines that either (x) such Intellectual Property Collateral is of negligible economic value to such Grantor or (y) the loss of such Intellectual Property Collateral would not be material to such Grantor;
- (b) such Grantor shall promptly notify the Administrative Agent if it knows that any application or registration relating to any material item of the Intellectual Property Collateral may, in the Grantor's reasonable commercial judgment, become abandoned or dedicated to the public or placed in the public domain or invalid or unenforceable, or of any adverse determination (including the institution of, or any such determination in, any proceeding in the USPTO, the USCO or any foreign counterpart thereof or any court) regarding such Grantor's ownership of any of the Intellectual Property Collateral, its right to register the same or to keep and maintain and enforce the same;

(c) deliver, on a quarterly basis, together with the delivery of the applicable Compliance Certificate for such quarter, a report listing all applications for the registration of any Intellectual Property Collateral with the USPTO or any similar office or agency in any other country or any political subdivision thereof filed during such quarter, and upon the request of the Administrative Agent (subject to the terms of the Credit Agreement and this Security Agreement), the applicable Grantor shall execute and deliver all agreements, instruments and documents as the Administrative Agent may reasonably request to evidence the Administrative Agent's security interest in any Intellectual Property Collateral;

(d) [reserved]

- (e) such Grantor will take all reasonable and necessary steps (in such Grantor's reasonable business judgement), including in any proceeding before the USPTO, the USCO or any similar office or agency in any other country or any political subdivision thereof (subject to the terms of the Credit Agreement), to maintain and pursue any material application (and to obtain the relevant registration) filed with respect to, and to maintain any registration of, material Intellectual Property Collateral, including the filing of applications for renewal, affidavits of use, affidavits of incontestability and opposition, interference and cancellation proceedings and the payment of fees and taxes (except to the extent that dedication, abandonment or invalidation is permitted under the foregoing <u>clause (a)</u> or (b)); and
- (f) such Grantor will promptly (but no less than quarterly and sooner if requested by Administrative Agent) execute and deliver to the Administrative Agent (as applicable) a Patent Security Agreement, Trademark Security Agreement and/or Copyright Security Agreement, as the case may be, in the forms of Exhibit A, Exhibit B and Exhibit C hereto following its obtaining an interest in any such Intellectual Property and shall execute and deliver to the Administrative Agent any other document reasonably required to evidence the Administrative Agent's interest in any part of such item of Intellectual Property Collateral unless such Grantor shall determine in good faith (with the consent of the Administrative Agent, such consent not to be unreasonably withheld) that any Intellectual Property Collateral is of negligible economic value to such Grantor.

SECTION 4.6. As to Letter of Credit Rights.

- (a) Each Grantor, by granting a security interest in its Letter of Credit Rights to the Administrative Agent, intends to (and hereby does) collaterally assign to the Administrative Agent its rights (including its contingent rights) to the Proceeds of all Letter of Credit Rights of which it is or hereafter becomes a beneficiary or assignee.
- (b) Upon the occurrence of an Event of Default, such Grantor will, promptly upon request by the Administrative Agent, (i) notify (and such Grantor hereby authorizes the Administrative Agent to notify) the issuer and each nominated person with respect to each of the Letters of Credit that the Proceeds thereof have been assigned to the Administrative Agent hereunder and any payments due or to become due in respect thereof are to be made directly to the Administrative Agent and (ii) arrange for the Administrative Agent to become the transferee beneficiary of such Letter of Credit.

SECTION 4.7. <u>As to Commercial Tort Claims</u>. Each Grantor covenants and agrees that, until the Termination Date, with respect to any Commercial Tort Claim exceeding \$500,000 hereafter arising, it shall deliver to the Administrative Agent a reasonably detailed description of any such new Commercial Tort Claim.

SECTION 4.8. Electronic Chattel Paper and Transferable Records. If any Grantor at any time holds or acquires an interest in any Electronic Chattel Paper or any "transferable record," as that term is defined in Section 201 of the U.S. Federal Electronic Signatures in Global and National Commerce Act or in Section 16 of the U.S. Uniform Electronic Transactions Act, as in effect in any relevant jurisdiction, with a value in excess of \$500,000, such Grantor shall promptly notify the Administrative Agent thereof and, at the request of the Administrative Agent, shall take such action as the Administrative Agent may reasonably request to vest in the Administrative Agent control under Section 9-105 of the UCC of such Electronic Chattel Paper or control under Section 201 of the Federal Electronic Signatures in Global and National Commerce Act or, as the case may be, Section 16 of the Uniform Electronic Transactions Act, as so in effect in such jurisdiction, of such transferable record. The Administrative Agent agrees with such Grantor that the Administrative Agent will arrange, pursuant to procedures reasonably satisfactory to the Administrative Agent and so long as such procedures will not result in the Administrative Agent's loss of control, for the Grantor to make alterations to the Electronic Chattel Paper or transferable record permitted under Section 9-105 of the UCC or, as the case may be, Section 201 of the U.S. Federal Electronic Signatures in Global and National Commerce Act or Section 16 of the U.S. Uniform Electronic Transactions Act for a party in control to allow without loss of control, unless an Event of Default has occurred and is continuing or would occur after taking into account any action by such Grantor with respect to such Electronic Chattel Paper or transferable record.

- SECTION 4.9. Further Assurances, Etc. Each Grantor agrees that, from time to time at its own expense, it will, subject to the terms of this Security Agreement, promptly execute and deliver all further instruments and documents, and take all further action, that may be necessary or that the Administrative Agent may reasonably request, in order to perfect, preserve and protect any security interest granted hereby or to enable the Administrative Agent to exercise and enforce its rights and remedies hereunder with respect to any Collateral. Without limiting the generality of the foregoing, such Grantor will:
- (a) from time to time upon the written request of the Administrative Agent, promptly deliver to the Administrative Agent such stock powers, instruments and similar documents, reasonably satisfactory in form and substance to the Administrative Agent, with respect to Capital Securities constituting Collateral as are necessary to perfect the security interest created hereunder and will, from time to time upon the prior written request of the Administrative Agent, after the occurrence and during the continuance of any Event of Default, promptly transfer any Capital Securities constituting Collateral into the name of any nominee designated by the Administrative Agent; if any Collateral shall be evidenced by an Instrument, negotiable Document, Promissory Note or tangible Chattel Paper, deliver and pledge to the Administrative Agent hereunder such Instrument, negotiable Document, Promissory Note or tangible Chattel Paper (other than any Intercompany Note, any Instrument, negotiable

Document, Promissory Note or tangible Chattel Paper held in a Securities Account subject to a Control Agreement or any Instrument, negotiable Document, Promissory Note or tangible Chattel Paper not exceeding \$500,000 in principal amount individually) duly endorsed and accompanied by duly executed instruments of transfer or assignment, all in form and substance reasonably satisfactory to the Administrative Agent;

- (b) file (and hereby authorize the Administrative Agent to file) such Financing Statements or continuation statements, or amendments thereto, and such other instruments or notices (including any assignment of claim form under or pursuant to the federal assignment of claims statute, 31 U.S.C. § 3727, any successor or amended version thereof or any regulation promulgated under or pursuant to any version thereof), as may be necessary or that the Administrative Agent may reasonably request in order to perfect and preserve the security interests and other rights granted or purported to be granted to the Administrative Agent, for the benefit of the Secured Parties, hereby;
 - (c) [reserved];
- (d) not take or omit to take any action the taking or the omission of which would result in any impairment or alteration of any obligation of the maker of any Payment Intangible or other Instrument constituting Collateral, except as provided in <u>Section 4.4</u>; and
- (e) not create any tangible Chattel Paper with a value in excess of \$500,000 individually or \$1,000,000 in the aggregate, without placing a legend on such tangible Chattel Paper reasonably acceptable to the Administrative Agent indicating that the Administrative Agent has a security interest in such Chattel Paper.

With respect to the foregoing and the grant of the security interest hereunder, each Grantor hereby authorizes the Administrative Agent to file one or more financing or continuation statements, and amendments thereto, relative to all or any part of the Collateral as may be necessary or desirable to create, preserve, perfect or maintain the perfection of or validate the security interest granted hereunder. Each Grantor agrees that a carbon, photographic or other reproduction of this Security Agreement or any UCC financing statement covering the Collateral or any part thereof shall be sufficient as a UCC financing statement where permitted by Law. Each Grantor hereby authorizes the Administrative Agent to file financing statements describing as the collateral covered thereby "all of the debtor's personal property or assets" or words to that effect, notwithstanding that such wording may be broader in scope than the Collateral described in this Security Agreement.

ARTICLE V THE ADMINISTRATIVE AGENT

- SECTION 5.1. <u>Agent Appointed Attorney-in-Fact</u>. Each Grantor hereby designates and appoints the Administrative Agent, on behalf of the Secured Parties, and each of its designees or agents, as attorney-in-fact of such Grantor, irrevocably and with power of substitution, with authority to take any or all of the following actions upon the occurrence and during the continuance of an Event of Default until the Termination Date in accordance with the terms hereof:
- (a) to demand, collect, settle, compromise and adjust, and give discharges and releases concerning the Collateral, all as the Administrative Agent may deem reasonably appropriate;
- (b) to commence and prosecute any actions at any court for the purposes of collecting any of the Collateral and enforcing any other right in respect thereof;
- (c) to defend, settle or compromise any action brought in respect of the Collateral and, in connection therewith, give such discharge or release as the Administrative Agent may deem reasonably appropriate;
 - (d) to pay or discharge taxes, liens, security interests or other encumbrances levied or placed on or threatened against the Collateral;
- (e) to direct any parties liable for any payment in connection with any of the Collateral to make payment of any and all monies due and to become due thereunder directly to the Administrative Agent or as the Administrative Agent shall direct;
- (f) to receive payment of and receipt for any and all monies, claims, and other amounts due and to become due at any time in respect of or arising out of any Collateral;
- (g) to sign and endorse any drafts, assignments, proxies, stock powers, verifications, notices and other documents relating to the Collateral;
- (h) to execute and deliver all assignments, conveyances, statements, financing statements, renewal financing statements, security and pledge agreements, affidavits, notices and other agreements, instruments and documents that the Administrative Agent may deem reasonably appropriate in order to perfect and maintain the security interests and liens granted in this Agreement and in order to fully consummate all of the transactions contemplated therein;
- (i) to exchange any of the Collateral or other property upon any merger, consolidation, reorganization, recapitalization or other readjustment of the issuer thereof and, in connection therewith, deposit any of the Collateral with any committee, depository, transfer agent, registrar or other designated agency upon such terms as the Administrative Agent may deem reasonably appropriate;
- (j) to vote for a shareholder or member resolution, or to sign an instrument in writing, sanctioning the transfer of any or all of the Collateral into the name of the Administrative Agent or one or more of the Secured Parties or into the name of any transferee to whom the Collateral or any part thereof may be sold pursuant to Article VI hereof; and
 - (k) to perform the affirmative obligations of such Grantor hereunder.

This power of attorney is a power coupled with an interest and shall be irrevocable for so long as any of the Obligations (other than contingent indemnification obligations for which no claim has been asserted) shall remain outstanding and until all of the commitments relating thereto shall have been terminated. The Administrative Agent shall be under no duty to exercise or withhold the exercise of any of the rights, powers, privileges and options expressly or implicitly

granted to the Administrative Agent in this Agreement, and shall not be liable for any failure to do so or any delay in doing so. The Administrative Agent shall not be liable for any act or omission or for any error of judgment or any mistake of fact or law in its individual capacity or its capacity as attorney-in-fact except acts or omissions resulting from its gross negligence or willful misconduct. This power of attorney is conferred on the Administrative Agent solely to protect, preserve and realize upon its security interest in the Collateral.

SECTION 5.2. <u>Assignment by the Administrative Agent</u>. The Administrative Agent may from time to time assign its security interest in the Collateral to a successor agent in accordance with the Credit Agreement, and the assignee shall be entitled to all of the rights and remedies of the Administrative Agent under this Agreement in relation thereto.

SECTION 5.3. The Administrative Agent's Duty of Care. Other than the exercise of reasonable care to assure the safe custody of the Collateral while being held by the Administrative Agent hereunder and to account for all proceeds thereof, the Administrative Agent shall have no duty or liability to preserve rights pertaining thereto, it being understood and agreed that the Grantors shall be responsible for preservation of all rights in the Collateral, and the Administrative Agent shall be relieved of all responsibility for the Collateral upon surrendering it or tendering the surrender of it to the Grantors. The Administrative Agent shall be deemed to have exercised reasonable care in the custody and preservation of the Collateral in its possession if such Collateral is accorded treatment substantially equal to that which the Administrative Agent accords its own property, which shall be no less than the treatment employed by a reasonable and prudent agent in the industry, it being understood that the Administrative Agent shall not have responsibility for (i) ascertaining or taking action with respect to calls, conversions, exchanges, maturities, tenders or other matters relating to any Collateral, whether or not the Administrative Agent has or is deemed to have knowledge of such matters or (ii) taking any necessary steps to preserve rights against any parties with respect to any of the Collateral. The provisions of Article XI of the Credit Agreement, including the rights, privileges, protections, benefits, indemnities and immunities of the Administrative Agent are incorporated herein, mutatis mutandis, as if a part hereof, and shall also apply to the Administrative Agent acting under or in connection with this Agreement.

SECTION 5.4. <u>Release of Collateral</u>. The Administrative Agent, upon the direction of the Required Lenders, may release any of the Collateral from this Security Agreement or may substitute any of the Collateral for other Collateral without altering, varying or diminishing in any way the force, effect, lien, pledge or security interest of this Agreement as to any Collateral not expressly released or substituted, and this Agreement shall continue as a first priority (subject to Permitted Liens) lien on all Collateral not expressly released or substituted.

SECTION 5.5. <u>Application of Proceeds</u>. Upon the occurrence and during the continuation of an Event of Default, any payments in respect of the Obligations and any proceeds of the Collateral, when received by the Administrative Agent or any of the Secured Parties in cash or its equivalent, will be applied in reduction of the Obligations in the order set forth in Section 9.4 of the Credit Agreement, and each Grantor irrevocably waives the right to direct the application of such payments and proceeds and acknowledges and agrees that the Administrative Agent shall have the continuing and exclusive right to apply and reapply any and all such payments and proceeds in accordance with Section 9.4 of the Credit Agreement.

ARTICLE VI REMEDIES

SECTION 6.1. Certain Remedies. If any Event of Default shall have occurred and be continuing:

- (a) The Administrative Agent may exercise in respect of the Collateral, in addition to other rights and remedies provided for herein or otherwise available to it, all the rights and remedies of the Administrative Agent on default under the UCC (whether or not the UCC is in effect in the jurisdiction where the rights and remedies are asserted) and also may:
 - (i) take possession of any Collateral not already in its possession without demand and without legal process;
- (ii) require each Grantor to, and each Grantor hereby agrees that it will, at its expense and upon request of the Administrative Agent forthwith, assemble all or part of the Collateral as reasonably directed by the Administrative Agent and make it available to the Administrative Agent at a place to be designated by the Administrative Agent that is reasonably convenient to both the Administrative Agent and such Grantor;
- (iii) enter onto the property where any Collateral is located and take possession thereof without demand and without legal process; and
- (iv) without notice except as specified below, lease, license, sell or otherwise dispose of the Collateral or any part thereof in one or more parcels at any public or private sale, at any of the Administrative Agent's offices or elsewhere, for cash, on credit or for future delivery, and upon such other terms as the Administrative Agent may deem commercially reasonable. Each Grantor agrees that, to the extent notice of sale shall be required by Law, at least ten (10) days' prior notice to such Grantor of the time and place of any public sale or the time after which any private sale is to be made shall constitute reasonable notification. The Administrative Agent shall not be obligated to make any sale of Collateral regardless of notice of sale having been given. The Administrative Agent may adjourn any public or private sale from time to time by announcement at the time and place fixed therefor, and such sale may, without further notice, be made at the time and place to which it was so adjourned.
- (b) All cash Proceeds received by the Administrative Agent in respect of any sale of, collection from, or other realization upon, all or any part of the Collateral shall be applied by the Administrative Agent against all or any part of the Obligations as set forth in Section 9.4 of the Credit Agreement.
 - (c) The Administrative Agent may:
- (i) transfer all or any part of the Collateral into the name of the Administrative Agent or its nominee, with or without disclosing that such Collateral is subject to the Lien hereunder;
- (ii) notify the parties obligated on any of the Collateral to make payment to the Administrative Agent of any amount due or to become due thereunder;

- (iii) withdraw, or cause or direct the withdrawal, of all funds with respect to any Collateral Account;
- (iv) enforce collection of any of the Collateral by suit or otherwise, and surrender, release or exchange all or any part thereof, or compromise or extend or renew for any period (whether or not longer than the original period) any obligations of any nature of any party with respect thereto;
 - (v) endorse any checks, drafts, or other writings in any Grantor's name to allow collection of the Collateral;
 - (vi) take control of any Proceeds of the Collateral; and
- (vii) execute (in the name, place and stead of any Grantor) endorsements, assignments, stock powers and other instruments of conveyance or transfer with respect to all or any of the Collateral.
- SECTION 6.2. <u>Securities Laws</u>. If the Administrative Agent shall determine to exercise its right to sell all or any of the Collateral that are Capital Securities pursuant to <u>Section 6.1(a)(iv</u>), each Grantor agrees that, upon written request of the Administrative Agent, such Grantor will, at its own expense:
- (a) execute and deliver, and cause (or, with respect to any issuer which is not a Subsidiary of such Grantor, use its best efforts to cause) each issuer of the Collateral contemplated to be sold and the directors and officers thereof to execute and deliver, all such instruments and documents, and do or cause to be done all such other acts and things, as may be necessary or, in the opinion of the Administrative Agent, advisable to register such Collateral under the provisions of the Securities Act of 1933, as from time to time amended and the rules and regulations of the SEC thereunder (the "Securities Act"), and cause the registration statement relating thereto to become effective and to remain effective for such period as prospectuses are required by Law to be furnished, and to make all amendments and supplements thereto and to the related prospectus which, in the opinion of the Administrative Agent, are necessary or advisable, all in conformity with the requirements of the Securities Act and the rules and regulations of the SEC applicable thereto;
- (b) use its best efforts to exempt the Collateral under the state securities or "<u>Blue Sky</u>" laws and to obtain all necessary governmental approvals for the sale of the Collateral, as requested by the Administrative Agent;
- (c) cause (or, with respect to any issuer that is not a Subsidiary of such Grantor, use its best efforts to cause) each such issuer to make available to its security holders, as soon as practicable, an earnings statement that will satisfy the provisions of Section 11(a) of the Securities Act; and
- (d) do or cause to be done all such other acts and things as may be necessary to make such sale of the Collateral or any part thereof valid and binding and in compliance with applicable Law.

SECTION 6.3. <u>Compliance with Restrictions</u>. Each Grantor agrees that in any sale of any of the Collateral whenever an Event of Default shall have occurred and be continuing, the Administrative Agent is hereby authorized to comply with any limitation or restriction in connection with such sale as it may be advised by counsel is necessary in order to avoid any violation of applicable Law (including compliance with such procedures as may restrict the number of prospective bidders and purchasers, require that such prospective bidders and purchasers have certain qualifications, and restrict such prospective bidders and purchasers to Persons who will represent and agree that they are purchasing for their own account for investment and not with a view to the distribution or resale of such Collateral), or in order to obtain any required approval of the sale or of the purchaser by any Governmental Authority or official, and such Grantor further agrees that such compliance shall not result in such sale being considered or deemed not to have been made in a commercially reasonable manner, nor shall the Administrative Agent be liable nor accountable to such Grantor for any discount allowed by the reason of the fact that such Collateral is sold in compliance with any such limitation or restriction.

SECTION 6.4. <u>Protection of Collateral</u>. The Administrative Agent may from time to time, at its option, upon the occurrence and continuance of an Event of Default, perform and take any action which the Administrative Agent deems reasonably necessary for the maintenance, preservation or protection of any of the Collateral or of its security interest therein.

ARTICLE VII MISCELLANEOUS PROVISIONS

- SECTION 7.1. <u>Loan Document</u>. This Security Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.
- SECTION 7.2. <u>Binding on Successors, Transferees and Assigns; Assignment</u>. This Security Agreement shall remain in full force and effect until the Termination Date has occurred, shall be binding upon the Grantors and their successors, permitted transferees and permitted assigns and shall inure to the benefit of and be enforceable by the Administrative Agent and the Secured Parties; <u>provided</u> that no Grantor may assign or transfer any of its rights or obligations hereunder without the prior consent of the Administrative Agent.
- SECTION 7.3. <u>Amendments, Etc.</u> No amendment or modification to or waiver of any provision of this Security Agreement, nor consent to any departure by any Grantor from its obligations under this Security Agreement, shall in any event be effective unless the same shall be in writing and signed by the Administrative Agent and the Grantors and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.
- SECTION 7.4. <u>Notices</u>. All notices and other communications provided for hereunder shall be delivered or made as provided in Section 10.2 of the Credit Agreement.
- SECTION 7.5. Release of Liens. Upon (a) the Disposition of Collateral to a Person that is not a Grantor or a Subsidiary of a Grantor in accordance with the Credit Agreement and (b) the occurrence of the Termination Date, the security interests granted herein shall automatically

terminate with respect to (i) such Collateral (in the case of <u>clause (a)</u>) or (ii) all Collateral (in the case of <u>clause (b)</u>). Upon any such Disposition or termination, the Administrative Agent will, at the Grantors' sole expense, deliver to the Grantors, without any representations, warranties or recourse of any kind whatsoever, all Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantors such documents as the Grantors shall reasonably request to evidence such termination. Upon the occurrence of the Termination Date, this Security Agreement shall automatically terminate.

SECTION 7.6. Additional Grantors. Upon the execution and delivery by any other Person of a supplement in the form of Annex I hereto, such Person shall become a "Grantor" hereunder with the same force and effect as if it were originally a party to this Security Agreement and named as a "Grantor" hereunder. The execution and delivery of such supplement shall not require the consent of any other Grantor hereunder, and the rights and obligations of each Grantor hereunder shall remain in full force and effect notwithstanding the addition of any new Grantor as a party to this Security Agreement. Any schedules delivered by any additional Grantor pursuant to such supplement shall supplement the relevant schedules to this Security Agreement.

SECTION 7.7. No Waiver; Remedies. In addition to, and not in limitation of Section 2.5, no failure on the part of the Administrative Agent to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right hereunder preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by Law.

SECTION 7.8. <u>Severability</u>. Any provision of this Security Agreement which is prohibited or unenforceable in any jurisdiction shall, as to such provision and such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of this Security Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

SECTION 7.9. Governing Law, Entire Agreement, Etc. THIS SECURITY AGREEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR ANY DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Security Agreement, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter thereof and supersedes any prior agreements, written or oral, with respect thereto.

SECTION 7.10. <u>Counterparts</u>. This Security Agreement may be executed by the parties hereto in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. This Security Agreement shall become effective when counterparts hereof executed on behalf of all of the signatories hereto, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Security Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Security Agreement.

SECTION 7.11. <u>Rights of Required Lenders</u>. If the Administrative Agent has resigned and no successor agent has been appointed pursuant to Section 10.10 of the Credit Agreement, all rights of the Administrative Agent hereunder may be exercised by the Required Lenders.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the parties hereto has caused this Security Agreement to be duly executed and delivered by its Authorized Officer as of the date first above written.

HARMONY BIOSCIENCES, LLC

By: /s/ John Jacobs

Name: John Jacobs

Title: Chief Executive Officer

HARMONY BIOSCIENCES II, LLC

By: /s/ John Jacobs

Name: John Jacobs

Title: Chief Executive Officer

[Signature Page to Security Agreement]

IN WITNESS WHEREOF, each of the parties hereto has caused this Security Agreement to be duly executed and delivered by its Authorized Officer as of the date first above written.

ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP

as the Administrative Agent

By: OrbiMed ROF III LLC, its General Partner

By: OrbiMed Advisors LLC, its Managing Member

By: /s/ W. Carter Neild

Name: W. Carter Neild Title: Member

[Signature Page to Security Agreement]

SCHEDULE I to Security Agreement

Name of Grantor: Harmony Biosciences II, Inc.

Interest:
100 units of membership interest in
Harmony Biosciences, LLC (100%)

Item A. Location of each Grantor.

Name of Grantor: Location for purposes of UCC: Address of Executive Office and

Principal Place of Business

Harmony Biosciences II, Inc. Delaware 630 W Germantown Pike, Suite 215, Plymouth

Meeting, Montgomery County, PA 19462

Harmony Biosciences, LLC Delaware 630 W Germantown Pike, Suite 215, Plymouth

Meeting, Montgomery County, PA 19462

Item B. Filing locations last five years.

Name of Grantor: Location for purposes of UCC:

Harmony Biosciences II, Inc.

Delaware

Harmony Biosciences, LLC

Delaware

Item C. <u>Trade names</u>.

None.

Item D. Merger or other corporate reorganization.

Harmony Biosciences II, Inc. was previously known as Harmony Biosciences II, LLC.

Item E. Grantor's federal taxpayer ID numbers.

Name of Grantor: Taxpayer ID numbers:

Harmony Biosciences II, Inc. 82-2279923 Harmony Biosciences, LLC 82-1608705

Item F. Government Contracts.

None.

Item G. <u>Deposit Accounts</u> , <u>Securities Accounts and Commodity Accounts</u> .
[Account Information]
Item H. <u>Letter of Credit Rights</u> .
None.
Item I. Commercial Tort Claims.
None.
Item J. <u>Pledged Notes</u> .
None.

Item A. Patents.

None.

Item B. Patent Licenses.

None.

Item A. <u>Trademarks</u>.

Owner	Trademark	Appl. #	Reg. #	Status	Country of Reg.	Appl. Dt	Reg. Dt
Harmony Biosciences, LLC	REM AT THE WRONG TIME	87954316	N/A	Published (Pending) Intent to Use	USA	6/8/19	N/A
Harmony Biosciences, LLC	NON-REM AT THE WRONG TIME	87954324	N/A	Published (Pending) Intent to Use	USA	6/8/19	N/A
Harmony Biosciences, LLC	KNOW NARCOLEPSY	87830683	5588181	Registered	USA	3/12/18	10/16/18
Harmony Biosciences, LLC	HARMONY BIOSCIENCES	87759175	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A
Harmony Biosciences, LLC	HARMONY BIOSCIENCES	87759246	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A
Harmony Biosciences, LLC	HB	87759250	N/A	Published (Pending) Intent to Use	USA	1/17/18	N/A

Domain Names:

abusewakix.com abusewakix.info abusewakix.net abusewakix.org againstwakix.com

againstwakix.info

againstwakix.net

againstwakix.org

dangersofwakix.com

dangersofwakix.info

dangersofwakix.net

dangersofwakix.org

donottakewakix.com

donottakewakix.info

donottakewakix.net

donottakewakix.org

harmonybiosci.info

harmonybiosci.net

harmonybiosci.org

harmonybiosciences.info

harmonybiosciences.net

harmonybiosciences.org

harmonybiosciencesllc.com

harmonybiosciencesllc.info

harmony biosciences llc.net

harmonybiosciencesllc.org

harmonybiosciencesllcsucks.com

harmonybiosciencesllcsucks.info

harmony biosciences llc sucks.net

harmonybiosciencesllcsucks.org

harmonybiosciencessucks.com

harmonybiosciencessucks.info

harmonybiosciencessucks.net

harmonybiosciencessucks.org

harmonybioscisucks.com

harmonybioscisucks.info

harmonybioscisucks.net

harmonybioscisucks.org

harmonysucks.com

harmonysucks.info

harmonysucks.net

harmonysucks.org

ihateharmony.com

ihateharmony.info

ihateharmony.net

ihateharmony.org

ihateharmonybiosci.com

ihateharmonybiosci.info

ihateharmonybiosci.net

ihateharmonybiosci.org

ihateharmonybiosciences.com

ihateharmonybiosciences.info

ihateharmonybiosciences.net

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ihateharmonybiosciencesllc.net

ihateharmonybiosciencesllc.org

ihatewakix.com

ihatewakix.info

ihatewakix.net

ihatewakix.org

knowmorenarcolepsy.com

knowmorenarcolepsy.info

knowmorenarcolepsy.net

knowmorenarcolepsy.org

knownarcolepsy.com

knownarcolepsy.info

knownarcolepsy.net

knownarcolepsy.org

knownarcolepsyhcp.com

knownarcolepsyhcp.net

knownarcolepsyhcp.org

nonarcolepsy.com

nonarcolepsy.info

nonarcolepsy.net

nonarcolepsy.org

pitolisant.com

pitolisant.info

pitolisant.net pitolisant.org pitolisant.us saynotoharmony.com saynotoharmony.info saynotoharmony.net saynotoharmony.org saynotoharmonybiosci.com saynotoharmonybiosci.info saynotoharmonybiosci.net saynotoharmonybiosci.org say not o harmony biosciences. comsaynotoharmonybiosciences.info saynotoharmonybiosciences.net saynotoharmonybiosciences.org saynotoharmonybiosciencesllc.com s ay not o harmony biosciences llc. in fosay not o harmony biosciences llc.netsaynotoharmonybiosciencesllc.org saynotowakix.com saynotowakix.info saynotowakix.net saynotowakix.org wakerix.com wakerix.info

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wakixeoupon.org wakixefficacy.com wakixefficacy.info wakixefficacy.net wakixefficacy.org

wakixformulary.com

wakixformulary.info

wakix formulary.net

wakixformulary.org

wakixformularyfinder.com

wakixformularyfinder.info

wakixformularyfinder.net

wakixformularyfinder.org

wakixforyou.com

wakixforyou.info

wakixforyou.net

wakixforyou.org

wakixhcp.com

wakixhcp.info

wakixhcp.net

wakixhcp.org

wakixhcpsupport.com

wakixhcpsupport.info

wakixhcpsupport.net

wakixhcpsupport.org

wakixinfo.com

wakixinfo.info

wakixinfo.net

wakixinfo.org

wakixisnotsafe.com

wakixisnotsafe.info

wakixisnotsafe.net

wakixisnotsafe.org

wakixkills.com

wakixkills.info

wakixkills.net

wakixkills.org

wakixlearnmore.com

wakixlearnmore.info

wakixlearnmore.net

wakixlearnmore.org

wakixmedinfo.com

wakixmedinfo.info

wakixmedinfo.net

wakixmedinfo.org

wakixnarcolepsy.com

wakixnarcolepsy.info

wakixnarcolepsy.net

wakixnarcolepsy.org

wakixpatient.com

wakixpatient.info

wakixpatient.net

wakixpatient.org

wakixpatientsolutions.com

wakix patient solutions. in fowakixpatientsolutions.net wakixpatientsolutions.org wakixreimbursement.com wakixreimbursement.info wakixreimbursement.net wakixreimbursement.org wakixrxassist.com wakixrxassist.info wakixrxassist.net wakixrxassist.org wakixrxconnect.com wakixrxconnect.info wakixrxconnect.net wakixrxconnect.org wakixsavingscard.com wakixsavingscard.info wakix saving scard.netwakixsavingscard.org wakixsucks.com wakixsucks.info wakixsucks.net wakixsucks.org

wakixsupportsolutions.com wakixsupportsolutions.info

wakixsupportsolutions.org
waxik.com
waxik.info
waxik.net
waxik.org
waxik.us
waxirem.com
waxirem.info
waxirem.net
waxirem.org

Item B. <u>Trademark Licenses</u>.

None.

Item A. Copyrights/Mask Works.

None.

Item B. Copyright/Mask Work Licenses.

None.

Trade Secret or Know-How Licenses

None.

PATENT SECURITY AGREEMENT

This PATENT SECURITY AGREEMENT, dated as of $[\bullet]$, 20__ (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a $[\bullet]$ (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, for the benefit of the Secured Parties, dated as of January 9, 2020 (as amended, supplemented or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Patent Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

- SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.
- SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Grantor's right, title and interest in and to the Patent Collateral, including each Patent and Patent application referred to in Item A of Schedule I attached hereto and each Patent license referred to in <u>Item B</u> of <u>Schedule I</u> attached hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).

- SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the Patent Collateral with the USPTO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.
- SECTION 4. Release of Liens. Upon (a) the Disposition of Patent Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Patent Collateral (in the case of clause (a)) or (ii) all Patent Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Patent Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.
- SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Patent Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.
- SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.
- SECTION 7. <u>Effectiveness</u>. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN	WITNESS WHEREOF, the Grantor hereto has caused this Agreement to be duly executed and delivered by its Authorized Office	cer as of the
date firs	above written.	

[NAME OF GRANTOR]

By:	
	Name:
	Title:

[Signature Page to Patent Security Agreement]

Item A. Patents.

Issued Patents

<u>Country</u> <u>Patent No.</u> <u>Issue Date</u> <u>Inventor(s)</u> <u>Title</u>

Pending Patent Applications

<u>Country</u> <u>Serial No.</u> <u>Filing Date</u> <u>Inventor(s)</u> <u>Title</u>

Item B. Patent Licenses (excluding any licenses to the Grantor for commercially available off-the-shelf software).

Country orEffectiveExpirationSubjectTerritoryLicensorLicenseeDateDateMatter

TRADEMARK SECURITY AGREEMENT

This TRADEMARK SECURITY AGREEMENT, dated as of [●], 20__ (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a [●] (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, dated as of January 9, 2020 (as amended, supplemented, or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Trademark Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

- SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.
- SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of Grantor's right, title and interest in and to the Trademark Collateral, including those Trademarks referred to in <u>Item B</u> of <u>Schedule I</u> hereto and each Trademark license referred to in <u>Item B</u> of <u>Schedule I</u> hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).
- SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the

Trademark Collateral with the USPTO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.

- SECTION 4. Release of Liens. Upon (a) the Disposition of Trademark Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Trademark Collateral (in the case of clause (a)) or (ii) all Trademark Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Trademark Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.
- SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Trademark Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.
- SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.
- SECTION 7. <u>Effectiveness</u>. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN WITNESS	WHEREOF, the Grantor here	eto has caused this Agr	reement to be duly	executed and delivered	d by Authorized	Officer as of the date
first above written.						

[NAME OF GRANTOR]

By:	
N	ame:
T	itle:
[Signature Page to Trademark Security Agreem	ent]

Item A. Trademarks.

Registered Trademarks

<u>Country</u> <u>Trademark</u> <u>Registration No.</u> <u>Registration Date</u>

Pending Trademark Applications

<u>Country</u> <u>Trademark</u> <u>Serial No.</u> <u>Filing Date</u>

Item B. Trademark Licenses.

Country or Effective Expiration
Territory Trademark Licensor Licensee Date Date

COPYRIGHT SECURITY AGREEMENT

This COPYRIGHT SECURITY AGREEMENT, dated as of [●], 20__ (this "<u>Agreement</u>"), is made by [NAME OF GRANTOR], a [●] (the "<u>Grantor</u>"), in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties.

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders (as defined therein) and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, in connection with the Credit Agreement, the Grantor and its Affiliates have executed and delivered a Pledge and Security Agreement in favor of the Administrative Agent, dated as of January 9, 2020 (as amended, supplemented or otherwise modified from time to time, the "Security Agreement");

WHEREAS, pursuant to the Credit Agreement and pursuant to clause (f) of Section 4.5 of the Security Agreement, the Grantor is required to execute and deliver this Agreement and to grant to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Copyright Collateral (as defined below) to secure all of the Obligations; and

WHEREAS, the Grantor has duly authorized the execution, delivery and performance of this Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor agrees, for the benefit of the Secured Parties, as follows:

- SECTION 1. <u>Definitions</u>. Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided (or incorporated by reference) in the Security Agreement.
- SECTION 2. <u>Grant of Security Interest</u>. The Grantor hereby grants to the Administrative Agent, for the benefit of the Secured Parties, a continuing security interest in all of the Grantor's right, title and interest in and to the Copyright Collateral, including the Copyrights referred to in <u>Item B</u> of <u>Schedule I</u> hereto and the exclusive Copyright licenses referred to in <u>Item B</u> of <u>Schedule I</u> hereto (excluding any licenses to the Grantor for commercially available off-the-shelf software).

- SECTION 3. <u>Security Agreement</u>. This Agreement has been executed and delivered by the Grantor for the purpose of registering the security interest of the Administrative Agent in the Copyright Collateral with the USCO. The security interest granted hereby has been granted in furtherance of, and not in limitation of, the security interest granted to the Administrative Agent for the benefit of the Secured Parties under the Security Agreement. The Security Agreement (and all rights and remedies of the Secured Parties thereunder) shall remain in full force and effect in accordance with its terms.
- SECTION 4. Release of Liens. Upon (a) the Disposition of Copyright Collateral in accordance with the Credit Agreement or (b) the occurrence of the Termination Date, the security interests granted herein shall automatically terminate with respect to (i) such Copyright Collateral (in the case of clause (a)) or (ii) all Copyright Collateral (in the case of clause (b)). Upon any such Disposition or termination, the Administrative Agent will, at the Grantor's sole expense, deliver to the Grantor, without any representations, warranties or recourse of any kind whatsoever, all Copyright Collateral held by the Administrative Agent hereunder, and execute and deliver to the Grantor such documents as the Grantor shall reasonably request to evidence such termination.
- SECTION 5. <u>Acknowledgment</u>. The Grantor does hereby further acknowledge and affirm that the rights and remedies of the Secured Parties with respect to the security interest in the Copyright Collateral granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which (including the remedies provided for therein) are incorporated by reference herein as if fully set forth herein.
- SECTION 6. <u>Loan Document</u>. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated herein) be construed, administered and applied in accordance with the terms and provisions thereof, including Article X thereof.
- SECTION 7. <u>Effectiveness</u>. This Agreement shall become effective when a counterpart hereof executed by the Grantor, shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF,	the Grantor hereto has caused this	Agreement to be duly	executed and delivered by i	ts Authorized Of	ficer as of the
date first above written.					

[NAME OF GRANTOR]

By:	
Ī	Name:
5	Γitle:
[Signature Page to Copyright Security Agreen	nent]

Item A. Copyrights/Mask Works.

Registered Copyrights/Mask Works

<u>Country</u> <u>Registration No.</u> <u>Registration Date</u> <u>Author(s)</u> <u>Title</u>

Copyright/Mask Work Pending Registration Applications

<u>Country</u> <u>Serial No.</u> <u>Filing Date</u> <u>Author(s)</u> <u>Title</u>

Item B.. Exclusive Copyright/Mask Work Licenses.

Country or Effective Expiration
Territory Licensor Licensee Date Date

SUPPLEMENT TO PLEDGE AND SECURITY AGREEMENT

This SUPPLEMENT, dated as of [●], 20__ (this "<u>Supplement</u>"), is to the Pledge and Security Agreement, dated as of January 9, 2020 (as amended, supplemented, amended and restated or otherwise modified from time to time, the "<u>Security Agreement</u>"), among the Grantors (such term, and other terms used in this Supplement, to have the meanings set forth in Article I of the Security Agreement, unless otherwise defined herein or if the context otherwise requires) from time to time party thereto, in favor of ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP, a Delaware limited partnership (together with its successors, transferees and assignees, the "<u>Administrative Agent</u>") for the Secured Parties (as defined below).

WITNESSETH:

WHEREAS, pursuant to the Credit Agreement, dated as of January 9, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "<u>Credit Agreement</u>"), by and among HARMONY BIOSCIENCES, LLC, a Delaware limited liability company (the "<u>Borrower</u>"), the Lenders and the Administrative Agent, the Lenders have extended Commitments to make Loans to the Borrower;

WHEREAS, pursuant to the provisions of Section 7.6 of the Security Agreement, each of the undersigned is becoming a Grantor under the Security Agreement; and

WHEREAS, each of the undersigned desires to become a "<u>Grantor</u>" under the Security Agreement in order to induce the Lenders to continue to extend Loans under the Credit Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the undersigned agrees, for the benefit of the Secured Parties, as follows.

SECTION 1. Party to Security Agreement, Etc. In accordance with the terms of the Security Agreement, by its signature below, each of the undersigned hereby irrevocably agrees to become a Grantor under the Security Agreement with the same force and effect as if it were an original signatory thereto and each of the undersigned hereby (a) agrees to be bound by and comply with all of the terms and provisions of the Security Agreement applicable to it as a Grantor and (b) represents and warrants that the representations and warranties made by it as a Grantor thereunder are true and correct as of the date hereof, unless stated to relate solely to an earlier date, in which case such representations and warranties shall be true and correct as of such earlier date. In furtherance of the foregoing, each reference to a "Grantor" or "Grantors" in the Security Agreement shall be deemed to include each of the undersigned.

SECTION 2. Schedules. Each of the undersigned hereby authorizes the Administrative Agent to add the information set forth on the Schedules to this Supplement to the correlative Schedules attached to the Security Agreement.

- SECTION 3. Representations. Each of the undersigned hereby represents and warrants that this Supplement has been duly authorized, executed and delivered by it and that this Supplement and the Security Agreement constitute its legal, valid and binding obligation, enforceable against it in accordance with its terms.
- SECTION 4. <u>Full Force of Security Agreement</u>. Except as expressly supplemented hereby, the Security Agreement shall remain in full force and effect in accordance with its terms.
- SECTION 5. Severability. Wherever possible each provision of this Supplement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Supplement shall be prohibited by or invalid under such Law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Supplement or the Security Agreement.
- SECTION 6. Governing Law, Entire Agreement, Etc. THIS SUPPLEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR ANY DOCUMENT CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK). This Supplement, along with the other Loan Documents, constitutes the entire understanding among the parties hereto with respect to the subject matter thereof and supersedes any prior agreements, written or oral, with respect thereto.
- SECTION 7. <u>Effectiveness</u>. This Supplement shall become effective with respect to a Grantor when a counterpart hereof executed by such undersigned Grantor shall have been received by the Administrative Agent. Delivery of an executed counterpart of a signature page to this Supplement by email (in "pdf" or "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Supplement.

[Signature Page Follows]

the date first above written.	
	NAME OF ADDITIONAL SUBSIDIARY]
	Ву:
	Name: Title:
	NAME OF ADDITIONAL SUBSIDIARY]
	Ву:
	Name:

IN WITNESS WHEREOF, each of the parties hereto has caused this Supplement to be duly executed and delivered by its Authorized Officer as of

[Signature Page to Security Agreement Supplement]

Title:

[COPY SCHEDULES FROM SECURITY AGREEMENT]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

LICENSE AND COMMERCIALIZATION AGREEMENT

THIS LICENSE AND COMMERCIALIZATION AGREEMENT ("<u>Agreement</u>") dated as of July 28, 2017 ("<u>Signing Date</u>") is entered into between Bioprojet Société Civile de Recherche, an independent (privately owned) research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France ("<u>Bioprojet SCR</u>" and together with its Affiliates, including Bioprojet Pharma SARL and Bioprojet Europe Ltd., "<u>Bioprojet</u>") and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 1033 Skokie Boulevard, Suite 600, Northbrook, Illinois 60062 ("<u>Partner</u>").

BACKGROUND

- A. Bioprojet has developed the Product (as defined below) and owns or controls certain patents, know-how and other intellectual property relating to the Product;
 - B. Partner has experience in marketing and distributing pharmaceutical products in the Partner Territory; and
- C. Partner and Bioprojet wish to enter into an agreement whereby Bioprojet will grant to Partner, and Partner will obtain, certain exclusive rights and licenses under the Licensed Assets to Commercialize the Product in the Field and the Partner Territory, provided that Bioprojet will retain the right to develop and Commercialize the Product anywhere in the world for the Bioprojet Territory, all on the terms and conditions set forth herein and therein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

Article 1

DEFINITIONS

In addition to the capitalized terms defined elsewhere in this Agreement, the following terms shall have the meanings set forth below, except as otherwise provided herein.

1.1 "Affiliate" of a Party shall mean any person, corporation or other entity that, directly or indirectly, controls, is controlled by, or is under common control with such Party, as the case may be. As used in this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") shall mean the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting share capital in such person, corporation, or other entity, or by contract or otherwise.

- 1.2 "Annual Net Sales" means, with respect to a particular Contract Year, all Net Sales during such Contract Year.
- **1.3** "API" shall mean the active pharmaceutical ingredient pitolisant hydrochloride (INN).
- **1.4** "Assigned Contracts" shall mean the contracts and agreements, if any, to which Bioprojet is a party, or by which Bioprojet is bound, relating to the Product and that may be assigned (in whole or in part) to Partner by Bioprojet pursuant to Section 9.3(e) of this Agreement, all of which are listed on Exhibit 1.4 attached hereto.
- 1.5 "Bioprojet Cost of Goods" shall mean, with respect to API or Product ordered by and delivered to Partner pursuant to the Supply Agreement, (a) to the extent manufactured by Third Party contractor(s) of Bioprojet, (i) the actual amount paid by Bioprojet to such Third Party contractor for such API or Product (or any component thereof), plus (ii) Bioprojet's direct labor costs and reasonably allocated overhead, in each case, specifically allocable to the oversight of manufacture and supply of such API or Product (or any component thereof) by such Third Party contractor, calculated in accordance with generally accepted accounting principles and Bioprojet's then prevailing standard procedures for calculating cost of goods, applied consistently across all of Bioprojet's products, and (b) to the extent manufactured by Bioprojet, Bioprojet's actual costs of materials, direct labor costs, reasonably allocated overhead (but excluding allocation of idle capacity), and quality control and testing costs, in each case specifically allocable to the production and delivery of such API or Product (or any component thereof), calculated in accordance with generally accepted accounting principles and Bioprojet's then prevailing standard procedures for calculating cost of goods, applied consistently across all of Bioprojet's products.
- **1.6** "Bioprojet Know-How" shall mean all scientific, medical, technical, regulatory and other information relating to the Product (including the Data), to the extent Controlled by Bioprojet as of the Signing Date or during the Term of this Agreement, and needed by or reasonably useful to Partner in order for Partner to Commercialize the Product in the Partner Territory.
- **1.7** "<u>Bioprojet Patents</u>" shall mean the Patents listed on <u>Exhibit 1.7</u>, together with all additions, divisions, continuations, substitutions, re-issues, re-examinations, registrations, patent term extensions, supplemental protection certificates, and renewals of any such Patents, as well as any other Patents Controlled by Bioprojet during the Term and covering the manufacture, use or sale of the Product.
 - 1.8 "Bioprojet Territory" shall mean all countries in the world other than the Partner Territory.
- **1.9** "Calendar Quarter" shall mean each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31.
 - **1.10** "Clearance Date" shall mean the date on which the HSR waiting period expires or is terminated.

- **1.11** "Clinical Studies" shall mean any clinical studies with respect to the Product, including Phase 1 Studies, Phase 2 Studies, Phase 3 Studies, Phase 4 Studies and IST's.
- **1.12** "Commercialization" shall mean, with respect to the Product, any and all processes and activities directed to selling, offering for sale (including any application for pricing and reimbursement approvals and more generally, any pricing, reimbursement and market access activities), distributing, detailing, marketing, advertising, promoting, storing, transporting, distributing, importing, and other commercial exploitation activities; provided, however, that Commercialization shall exclude Development and manufacturing activities (including manufacturing activities related to Commercialization). "Commercialize" and "Commercializing" shall have their correlative meanings.
- **1.13** "Contract Year" shall mean each period of time comprised of four consecutive, full Calendar Quarters following the First Commercial Sale of Product by Partner. For clarity, the first Contract Year shall mean the first four consecutive, full Calendar Quarters following the First Commercial Sale of Product by Partner, the second Contract Year shall mean the immediately subsequent four Calendar Quarters, and so forth.
- 1.14 "Control" (including any variations such as "Controlled" and "Controlling"), in the context of trademarks, know-how, Patents and other intellectual property rights, data and/or other information or assets, shall mean that such Party or its Affiliate owns or possesses rights to such trademarks, know-how, Patents and other intellectual property rights, data and/or other information or assets, as applicable, sufficient to grant the applicable license or sublicense under this Agreement.
- **1.15** "<u>Data</u>" shall mean, subject to Section 4.3(d), any and all research data, pharmacology data, preclinical data, clinical data and/or all Regulatory Filings and/or other regulatory documentation, information and submissions pertaining to, or made in association with a IND, NDA or Regulatory Approval, for the Product, in each case to the extent Controlled by a Party as of the Signing Date or during the Term of this Agreement.
- 1.16 "Development" or "Develop" shall mean non-clinical and clinical research and drug development activities, including toxicology, pharmacology, statistical analysis, Clinical Studies (including pre- and post-approval studies and Investigator Sponsored Clinical Studies), regulatory affairs, and regulatory activities pertaining to designing and carrying out Clinical Studies and obtaining Regulatory Approvals (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).
 - **1.17** "Effective Date" shall mean the date on which the Closing occurs.
 - **1.18** "FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.
- **1.19** "Field" shall mean the diagnosis, therapeutic treatment and/or prevention of (a) Narcolepsy (including Type 1 (with Cataplexy) and indication(s) Type 2 and the sleepiness associated therewith), obstructive sleep apnea (OSA), idiopathic hypersomnia, and Parkinson's disease; and (b) any other indication(s) unanimously agreed upon by the Parties.

- **1.20** "Field Products" shall mean any pharmaceutical product which is under development for, or has received Regulatory Approval in, one or more indications in the Field, other than the Product.
- **1.21** "First Commercial Sale" shall mean the first bona fide, arm's length sale of the Product in the Partner Territory following receipt of FDA approval of the first NDA for the Product in the Partner Territory.
- **1.22** "Generic Product" shall mean, with respect to the Product, any prescription pharmaceutical product other than the Product that (a) contains the API and (b) is "therapeutically equivalent" to the Product as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").
- **1.23** "Governmental Authority" shall mean any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, region, or international community or (ii) a supranational, federal, state, province, county, city or other political subdivision thereof, including the FDA, any of which has binding jurisdiction.
 - 1.24 "ICH Guidelines" shall mean the International Council for Harmonization guidelines, as amended from time to time.
- **1.25** "IND" shall mean an Investigational New Drug application (as such term is used in United States 21 C.F.R. Part 312, Subpart B) filed with the FDA for authorization to commence Clinical Studies).
- 1.26 "Investigator Sponsored Clinical Study." or "IST" shall mean a clinical or non-clinical study of a Product that is sponsored and conducted by a physician, physician group or other Third Party not acting under a license from or on behalf of a Party or an Affiliate, pursuant to an IND owned by such Third Party, and with respect to which a Party or its Affiliate provides clinical supplies of the Product, funding or other support for such clinical study.
- **1.27** "<u>Licensed Assets</u>" shall mean the Bioprojet Know-How, Bioprojet Patents, Product Trademarks, Product trade dress, Regulatory Filings and Regulatory Approvals.
- **1.28** "NDA" shall mean a New Drug Application, including all supplements and amendments thereto, for the approval of the Product by the FDA.
- 1.29 "Net Sales" shall mean, with respect to the Product for any period, the gross amounts billed or invoiced or otherwise received for sales of the Product in the Partner Territory to Third Parties by or on behalf of Partner, its Affiliates and/or Sublicensees, as the case may be, after Regulatory Approval of the applicable Product NDA in the Partner Territory, less the following deductions for costs incurred by Partner, its Affiliates and/or Sublicensees in connection with sales of the Product in the Partner Territory, to the extent solely related to the Product and calculated in accordance with United States Generally Accepted Accounting Principles

("<u>US GAAP</u>") and the accounting policies of Partner to the extent consistent with the US GAAP, its Affiliates and/or Sublicensees, as the case may be, consistently applied, for external reporting:

- (a) any normal and customary trade, quantity, prompt pay, cash and similar discounts or allowances (including, chargebacks and allowances but excluding payments and other amounts described in clause (f) below) actually granted, allowed or incurred in connection with the sale of the Product;
- (b) any normal and customary credits, rebates and allowances granted, allowed or incurred on account of (i) the rejection or return of the Product (including wholesaler and retailer returns and returns of expired or expiring Product), (ii) price adjustments affecting the Product, (iii) billing or quantity errors or (iv) recalls of the Product;
- (c) any costs actually paid to a Third Party by Partner or its Affiliates or Sublicensees for packing, packaging, transportation, importation, postage, shipping and handling charges for the Product, and other charges relating thereto, such as insurance and customs duties, and separately identified on the invoices or other documentation maintained in the ordinary course of business by Partner or its Affiliates or Sublicensees;
- (d) any sales, excise or value added taxes, other consumption taxes, and similar compulsory payments to, or charges by, Governmental Authorities imposed on or charged to Partner or its Affiliates or Sublicensees in connection with the sale of the Product and separately identified on the invoices or other documentation maintained in the ordinary course of business by Partner or its Affiliates or Sublicensees;
- (e) any actual bad debts actually written off by Partner or its Affiliates or Sublicensees, as reflected in its audited financial statements for the applicable reporting period or other documentation maintained in the ordinary course of business by Partner or its Affiliates or Sublicensees provided that if the debt is recovered it will be included in Net Sales; and
- (f) any reasonable rebates, reimbursements, fees or other payments or assistance by Partner or its Affiliates or Sublicensees to (i) wholesalers and other non-affiliated distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, government authorities, or other institutions or health care organizations with respect to the Product; or (ii) patients and other Third Parties (including charitable foundations) arising in connection with any patient assistance, co-pay assistance or similar programs applicable to the Product under which Partner or its Affiliates or Sublicensees provide to low income, uninsured or other patients the opportunity to obtain Partner's pharmaceutical products at no cost or reduced cost.

Product distributed by Partner or its Affiliates or Sublicensees (A) for promotional or sampling purposes, without payment or for non-monetary consideration or (B) for use in Clinical Studies shall be disregarded for purposes for calculating Net Sales.

Sales between Partner and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product shall be included within the computation of Net Sales.

1.30 "Partner Know-How" shall mean all marketing, regulatory and other information relating to the Product (including the Data), to the extent Controlled by Partner during the Term

of this Agreement, and needed by or reasonably useful to Bioprojet in order for Bioprojet to Develop and manufacture the Product for Commercialization outside the Partner Territory, to Commercialize the Product outside the Partner Territory, or perform its obligations under this Agreement. Notwithstanding the foregoing, Partner Know-How shall in any case include all such items that are generated by or under authority of Partner, or any of its Affiliates or Sublicensees, in connection with the Commercialization of the Product in the Partner Territory during the Term of this Agreement.

- 1.31 "Partner Territory," shall mean the United States and its territories, commonwealths and protectorates (including Puerto Rico).
- 1.32 "Party" shall mean Bioprojet or Partner, individually; and "Parties" shall mean Bioprojet and Partner, collectively.
- **1.33** "Patent(s)" shall mean any patents and patent applications, together with all additions, divisions, continuations, continued prosecution applications, continuations-in-part, substitutions, confirmations, validations, reissues, re-examinations, registrations, patent term extensions, supplemental protection certificates, restoration and renewals of any of the foregoing.
 - 1.34 "Phase 1 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(a).
 - 1.35 "Phase 2 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(b).
 - 1.36 "Phase 3 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(c).
- **1.37** "Phase 4 Studies" shall mean any study(ies) required by the FDA to be conducted after Regulatory Approval of a Product NDA in the Partner Territory as a condition to FDA granting such Regulatory Approval.
- **1.38** "Product" shall mean that certain product currently known, as of the Signing Date, as Wakix®, that contains the API as its sole active ingredient, as well as other delivery forms or dosages of Wakix that may be developed by the Parties pursuant to this Agreement.
- **1.39** "Product Liability Claim" shall mean any Third Party Claim that is commenced or threatened against a Party alleging product liability, product defect, design, packaging or labeling defect, failure to warn, or any similar action relating to the use or safety of those Products sold by or under authority of Partner in the Partner Territory.
- **1.40** "<u>Product Trademarks</u>" shall mean: (a) the product-specific trademarks owned or Controlled by Bioprojet and designated by Bioprojet for use with the Product, as reflected on <u>Exhibit 1.40</u>; and (b) any other product-specific trademarks that Bioprojet and Partner mutually agree upon for use with the Product in the Partner Territory during the Term of this Agreement.
- 1.41 "Regulatory Approval" shall mean, with respect to the Product in any country or jurisdiction, any and all approvals (including any pricing and reimbursement approvals, as

applicable), licenses, permits, certifications, registrations or authorizations of any Regulatory Authority necessary under applicable law in a country or other jurisdiction in order to commercially distribute, manufacture and have manufactured, sell or market the Product in such country or jurisdiction.

- **1.42** "Regulatory Authority" shall mean the FDA or any other regulatory body with similar regulatory authority within the Partner Territory or in any jurisdiction outside the Partner Territory.
- **1.43** "Regulatory Exclusivity" shall mean any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority in the Partner Territory, other than an issued and unexpired Patent, including any regulatory data protection exclusivity (including, where applicable, pediatric exclusivity and/or orphan drug exclusivity) and/or any exclusivity afforded by restrictions on the granting by a Regulatory Authority of regulatory approval to market a Generic Product in the Partner Territory.
- **1.44** "Regulatory Filing" shall mean all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs and NDA.
- **1.45** "Royalty Term" shall mean the period commencing on the First Commercial Sale of the Product in the Partner Territory by Partner or its Affiliates or Sublicensees and ending on the latest of (x) ten (10) years thereafter; (y) the last to expire Regulatory Exclusivity relating to the Product in the Partner Territory; or (z) the expiration of the last to expire Bioprojet Patent covering the manufacture, use or sale of the Product in the Partner Territory.
- **1.46** "Sublicensee" shall mean a Third Party that has been granted a right to Commercialize the Product in the Partner Territory pursuant to Section 2.2; and "Sublicense" shall mean an agreement or arrangement granting such rights. As used in this Agreement, "Sublicensee" shall not include a wholesaler or similar distributor or reseller of the Product who does not market or promote the Product (including, any specialty pharmacies).
- **1.47** "<u>Target Indications</u>" shall mean the treatment or prevention of (a) Narcolepsy, including treatment of Cataplexy ("<u>Narcolepsy with Cataplexy</u>" or Type 1); (b) excessive daytime sleepiness ("<u>EDS</u>" or Type 2); (c) obstructive sleep apnea ("<u>OSA</u>"); and (d) idiopathic hypersomnia ("<u>IH</u>").
- **1.48** "Transaction Documents" shall mean the Escrow Agreement, the Pharmacovigilance Agreement, the Supply Agreement, the Trademark License and the other agreements contemplated by and delivered pursuant to this Agreement.
 - **1.49** "Third Party" shall mean any person, corporation, or other entity, other than Bioprojet, Partner and their respective Affiliates.

Article 2

GRANT OF LICENSES

2.1 Licenses.

- (a) Exclusive Licenses. Subject to the terms and conditions of this Agreement, effective as of the Closing, Bioprojet hereby grants to Partner exclusive licenses, with the right to grant sublicenses as provided in Section 2.2, to the Product and the Licensed Assets to Commercialize the Product (including, to package and/or have packaged the Product, as supplied by Bioprojet under the Supply Agreement), solely in the Field in the Partner Territory. It is understood and agreed that the licenses set forth in this Section 2.1 exclude the right to manufacture or have manufactured the API contained in the Product, except to the extent set forth hereunder or in the Supply Agreement.
- (b) <u>Development License</u>. Subject to the terms and conditions of this Agreement, effective as of the Closing, Bioprojet hereby grants to Partner a co-exclusive (with Bioprojet and its Affiliates) license, with the right to grant sublicenses as provided in Section 2.2, under the Licensed Assets, to clinically Develop and register with Regulatory Authorities the Product, in the Field, in the Partner Territory.
- (c) <u>Certain Clarifications</u>. The rights and licenses granted to Partner in Section 2.1(a) shall be exclusive even as to Bioprojet and its Affiliates, except that, subject to the terms and conditions herein and of the Supply Agreement, Bioprojet retains the right to manufacture (or have manufactured) the Product in the Partner Territory for supply to Partner under the Supply Agreement, as well as for sale and use outside the Partner Territory. For clarity, it is understood that nothing in Section 2.1(a) shall prevent Bioprojet from publicizing the Product as a part of its pipeline at scientific meetings, trade conferences and the like. It is understood that during the Term, Partner shall not research, Develop or Commercialize any products containing the API other than the Product, shall not conduct research as to the Product and shall not clinically Develop or Commercialize the Product otherwise than as permitted pursuant to this Agreement. Subject to the licenses granted hereunder with respect to the Product and the terms and conditions of this Agreement including Section 2.3(b), Bioprojet retains the right to use (and right to grant licenses to Third Parties to use) the Licensed Assets to Develop and Commercialize products containing the API.

2.2 Sublicensees.

(a) Partner shall have the right, in accordance with this Section 2.2, to engage: (i) its Affiliates as sublicensees of the Product (including with respect to the Licensed Assets) in the Partner Territory; or (ii) to engage a Third Party(ies) as a Sublicensee(s) of the Product (including with respect to the Licensed Assets) in the Partner Territory subject to Bioprojet's express prior written consent not to be unreasonably withheld, conditioned or delayed. Partner may grant sublicenses to the rights and licenses granted to Partner under Section2.1 to such Affiliates and Third Parties solely on the terms set forth in this Section 2.2(a) and Section 2.2(b) below and, in the case of an Affiliate, solely for so long as such entity remains an Affiliate.

(b) In any event, Partner shall ensure that each of its Affiliates to whom Partner grants a sublicense pursuant to Section 2.2(a) and each Sublicensee is bound by a written agreement between Partner and such Affiliate or Sublicensee, as applicable, that does not conflict with, and contains provisions as protective of the Product and Bioprojet as, this Agreement. Without limiting any of Partner's obligations under this Agreement, Partner shall also ensure that each Affiliate to whom Partner grants a sublicense pursuant to Section 2.2(a) and each Sublicensee expressly agrees in writing to be bound by all of Partner's obligations under this Agreement to the extent applicable to such Affiliate or such Sublicensee. Partner shall remain responsible for any actions of its Affiliates and Sublicensees exercising sublicense rights under this Section 2.2 with respect to the rights and licenses granted by Bioprojet to Partner under this Agreement to the same extent as if such actions had been by Partner itself. Promptly following the execution of each Sublicense to a Sublicensee, Partner shall provide Bioprojet with an unredacted executed copy of such Sublicense; and Partner shall also provide to Bioprojet an unredacted executed copy of any amendment to a Sublicense that relates to the Product, promptly following the execution of each such amendment.

2.3 Activities Outside the Partner Territory.

- (a) To the extent permitted under applicable law, Partner agrees that neither it, nor any of its Affiliates, will sell or provide the Product to any Third Party and shall not allow its Sublicensees to sell or provide the Product to any Third Party, if Partner or its relevant Affiliate or Sublicensee knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use in the Bioprojet Territory.
- (b) To the extent permitted under applicable law, Bioprojet agrees that neither it, nor any of its Affiliates, will sell or provide the Product to any Third Party and shall not allow its Sublicensees to sell or provide the Product to any Third Party, if Bioprojet or its relevant Affiliate or Sublicensee knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use in the Field in Partner Territory; provided, however, that nothing in this Agreement (including this Section2.3(b)) shall be deemed to limit the rights retained by Bioprojet pursuant to Section 2.1(b) above.

2.4 No Other Rights.

- (a) Except for the rights and licenses expressly granted in this Agreement, Bioprojet retains all rights under its intellectual property, and no additional rights shall be deemed granted to Partner by implication, estoppel or otherwise.
- (b) In particular, except for the rights and licenses expressly granted in this Agreement, the rights and licenses granted to Partner under this Agreement do not include the right to, and Partner shall not, Develop or otherwise participate in Development activities for the Product without Bioprojet's prior written approval (including through the JSC) and an agreement as to the terms and conditions of such Development and the arising results.
- (c) For clarity, the licenses and rights granted to Partner in this Agreement shall not be construed to convey any licenses or rights under the Bioprojet Patents or the Bioprojet Know-How with respect to any subject matter other than a Product.

Article 3

GOVERNANCE

3.1 Joint Steering Committee.

(a) <u>Establishment</u>. Within thirty (30) calendar days following the Effective Date, Bioprojet and Partner shall establish a Joint Steering Committee ("<u>Joint Steering Committee</u>" or "<u>JSC</u>") to oversee, review and coordinate the clinical, regulatory, medical affairs, commercial and other strategies and activities of the Parties under this Agreement, including, the registration and Commercialization of the Product in the Field in the Partner Territory, subject to the provisions of this Article 3.

(b) <u>Duties</u>. The JSC shall:

- (i) Review and approve the clinical, regulatory, market access and price/branding positioning strategies for the Product in the Field in the Partner Territory (and substantive amendments and updates thereto);
- (ii) Review and approve the Initial Commercialization Plan and any substantive amendments, updates and other modifications thereto from time to time as provided for in this Agreement (the Initial Commercialization Plan, as so amended, updated or modified, shall be referred to as the "Commercialization Plan")) and oversee its implementation;
 - (iii) Review Partner's supply rolling forecast for the Product in accordance with the Supply Agreement;
- (iv) Review and approve any Clinical Studies (and any protocols thereof) intended to be conducted by or on behalf of the Partner or Bioprojet with respect to the Product (including any IST);
- (v) Provide a forum for the Parties: (A) to review, discuss and agree upon, as set forth in Section 3.4, material issues pertaining to the marketing, distribution and Commercialization of the Product in the Partner Territory, and matters pertaining to Regulatory Filings and Regulatory Approvals for the Product in the Partner Territory; and (B) to discuss their respective activities with respect to the foregoing matters;
 - (vi) Provide a forum for resolving matters referred to the JSC pursuant to the procedures set out in Section 3.4 below; and
 - (vii) Perform such other duties and responsibilities as are specifically assigned to the JSC in this Agreement.
- 3.2 <u>Membership</u>. The JSC shall be composed of an equal number of representatives from each of Partner and Bioprojet (or a Bioprojet Affiliate), selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of Partner and Bioprojet shall be, with respect to the JSC, three (3) representatives. Either Party may replace its respective JSC representatives at any time with prior written notice to the other Party; provided that the criteria for composition of the JSC set forth in the preceding sentence continues to be satisfied following any such replacement of a Party's representative on the JSC.

3.3 Meetings. The JSC shall meet at least once each Calendar Quarter, or at such other intervals as agreed to by the Parties. All JSC meetings may be conducted by telephone, video-conference or in person as determined by the JSC; provided that the JSC shall meet in person at least once each calendar year. Unless otherwise agreed by the Parties, all in-person meetings for the JSC shall be held on an alternating basis between Bioprojet's facilities and Partner's facilities. Each Party shall bear its own personnel and travel costs and expenses relating to JSC meetings. With the consent of the Parties (not to be withheld unreasonably), other appropriate employee representatives of the Parties may attend the JSC meeting as non-voting observers.

3.4 Decision-Making.

- (a) Subject to the remainder of this Section 3.4, decisions of the JSC shall be made by unanimous vote, with at least one (1) representative from each Party participating in any vote.
- (b) In the event that the JSC do not reach consensus with respect to a particular matter within five (5) business days after the matter is submitted to the JSC, then either Party may, by written notice to the other Party, have such matter referred to (i) Bioprojet's Chief Executive Officer on the part of Bioprojet and (ii) Partner's Chief Executive Officer on the part of Partner (collectively, "Senior Executives") who shall meet promptly and negotiate in good faith to attempt to resolve the dispute.
 - (c) If, despite such good faith efforts, the Senior Executives are unable to resolve such dispute during such meeting, then:
- (i) if such dispute relates to the Commercialization Plan (other than with respect to matters that relate to any proposed reduction of the level of resources to be committed by Partner under the Commercialization Plan, including the number of deployed sales representatives and the marketing and promotional spending, which matters shall be subject to clause (iv) below), the labeling of the Product (including negotiations with the FDA related thereto), regulatory activities or medical affairs strategies and activities in the Territory, Partner shall have the right to cast the deciding vote on such matter;
- (ii) if such dispute relates to the price/branding positioning strategy of the Product, Partner shall have the right to cast the deciding vote on such matter, provided that any change shall be duly justified by Partner by a significant market change;
- (iii) if such dispute relates to plans for any Clinical Study with respect to the Product (including any IST), such Clinical Study will not be conducted without Bioprojet's vote, unless such Clinical Study is required by any Regulatory Authority in the Partner Territory so as to maintain any Regulatory Approval in the Partner Territory;
- (iv) for any other matters to be decided by the JSC, including for clarity matters pertaining to any reduction to the overall level of resources to be committed by Partner under the Commercialization Plan, no such matters shall be implemented without unanimous consent of the Parties.

- (d) For clarity, neither Party shall have the right to cast a deciding vote to excuse itself from any of its obligations specifically enumerated under this Agreement.
- 3.5 Working Groups. From time to time, the JSC may establish and delegate duties to sub-committees or teams (each, a "Working Group") to oversee particular projects or activities within their respective authority, including clinical, regulatory, commercial, supply and pharmacovigilance. Each Working Group and its projects or activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. Any Working Group shall be composed of an equal number of representatives from each of Bioprojet and Partner, selected by such Party, and the total number of members of each Working Group will be determined by the JSC. Each Working Group shall meet at such times and in such places as directed by the JSC. In no event shall the authority of any Working Group exceed that specified for the JSC.
- 3.6 <u>Alliance Managers</u>. Within thirty (30) calendar days following the Effective Date, each Party shall appoint a representative ("<u>Alliance Manager</u>") to facilitate communications between the Parties and to act as a liaison between the Parties with respect to such other matters as the Parties may mutually agree in order to maximize the efficiency of this Agreement and the collaboration hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party.
- 3.7 Scope of Governance. Notwithstanding the creation of the JSC and/or any Working Group, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JSC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided in this Agreement, or the Parties expressly so agree in writing. The JSC shall not have the power to amend or modify this Agreement, and no decision of the JSC shall be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers under this Agreement and in no event shall the Alliance Managers have any power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by the JSC. It is also understood that the JSC shall not have any authority over activities related to the Development and/or Commercialization of the Product for use in the Bioprojet Territory.
- **3.8** <u>Day-to-Day Decision-Making Authority</u>. For the avoidance of doubt, Partner shall bear the entire responsibility of the Commercialization of the Product in the Partner Territory, provided that such decisions are not inconsistent with the Commercialization Plan or the terms and conditions of this Agreement.

Article 4

CLINICAL, REGULATORY AND MEDICAL AFFAIRS ACTIVITIES

4.1 Exchange of Data and Know-How.

- (a) <u>By Bioprojet</u>. Bioprojet or its Affiliates will make available to Partner, all Bioprojet Know-How relating to the Product that exists as of the Effective Date and is necessary, or materially useful, for Partner to Commercialize the Product in accordance with this Agreement, including all Data from Clinical Studies and preclinical studies for the Product that have been conducted by Bioprojet or its Affiliates prior to the Effective Date, in each case to the extent Controlled by Bioprojet or its Affiliates. Bioprojet shall make any such Data available in the original language in which such Data was generated, provided if such original language is not English, then Bioprojet shall provide English translations thereof.
- (b) <u>By Either Party</u>. During the Term of this Agreement, each Party shall provide to the other Party all such Party's know-how (i.e., in case of Bioprojet, Bioprojet Know-How, and in the case of Partner, Partner Know-How) (including, all Data from Clinical Studies and preclinical studies for the Product conducted by such Party or its Affiliates during the Term of this Agreement) that is Controlled by such Party or its Affiliates, is generated during the Term of this Agreement, is necessary, or materially useful to Commercialize the Product in the Field, and that has not previously been provided hereunder, in each case promptly upon request by the other Party. The Party providing such Party's know-how shall provide the same in electronic form to the extent the same exists in electronic form, and shall provide copies or an opportunity to inspect (and copy) for all other materials comprising such know-how (including, for example, original patient report forms and other original source data). Any Data provided by one Party to the other under this Subsection 4.1(b) shall be provided in the original language in which such Data was generated, provided if such original language is not English, then the Party supplying such Data shall also provide English translations thereof. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Bioprojet Know-How and the Partner Know-How under this Section 4.1(b).

4.2 Clinical Studies and Pre-Clinical Studies.

(a) Bioprojet shall be solely responsible (with input from Partner both through the JSC and otherwise), at Bioprojet's sole cost and expense, for conducting, to the best of its ability, any and all additional Clinical Studies (including, any pediatric studies) and/or preclinical studies (which may, in either case, require sites in the Partner Territory), whether pre-Regulatory Approval or post-Regulatory Approval, necessary, required or appropriate for obtaining and maintaining Regulatory Approval (including those relating to Phase 4 Studies) (a) in the Partner Territory of Product NDA's for (i) Narcolepsy (with or without Cataplexy), and (ii) for the subsequent indication of Cataplexy if a Cataplexy indication is not granted with the initial approval. All other costs associated with other regulatory activities for the Product performed by Partner, or otherwise agreed to be performed by Bioprojet by the JSC to the extent that it relates to the Field and the Territory during the Term in accordance with this Agreement, shall be borne by Partner.

- (b) With respect to additional Development activities necessary for obtaining or maintaining Regulatory Approval of the Product in the Partner Territory in indications in the Field other than Narcolepsy (with or without Cataplexy), the Parties may mutually agree through the JSC to a joint plan and budget pursuant to which they shall share the costs. In such case, the Party conducting such Development activities shall give access to the resulting Data to the other Party, which shall have the right to use them at no additional cost. If a Party does not agree to share the costs of such Development activities conducted by the other Party, such Party shall not have the right to use the resulting Data other than for safety reporting unless such Party pays the other Party seventy percent (70%) of its actual cost incurred in connection with such Development activities.
- (c) Bioprojet shall not perform any Clinical Studies or pre-clinical studies or any other Development activities related to the Product outside the Partner Territory, that are detrimental to the Commercialization of the Product by Partner in the Partner Territory.
- (d) Except for the Development activities as part of the Commercialization Plan for the Product within the Field after Regulatory Approval in the Territory or as otherwise provided in this Agreement, Partner shall not perform any Development activity within the Territory without obtaining the prior consent of Bioprojet, which shall not be unreasonably withheld, conditioned or delayed if such Development activity is required by the FDA to maintain the NDA.

4.3 Regulatory Submissions and Regulatory Approvals.

(a) Regulatory Responsibilities.

- (i) Subject to Section 4.3(a)(iii) of this Agreement, effective from and after the Effective Date, Bioprojet shall be responsible, using commercially reasonable efforts, for filing the initial NDA for the Product with the FDA, in Bioprojet's or Bioprojet Affiliate's name with Partner appointed as Bioprojet's designated US agent as required by the FDA. Upon approval of the first NDA by the FDA, Bioprojet shall transfer such NDA to Partner. Notwithstanding Partner holding the NDA in its name (or the name of its Affiliate), Bioprojet will maintain all rights as the licensor of the Product and the Licensed Assets.
- (ii) Subject to the provisions of Section 4.2, effective from and after the Effective Date, Partner shall be solely responsible for all pre-Regulatory Approval and post-Regulatory Approval costs associated with the regulatory and Commercialization activities with respect to the Product for the Partner Territory. Bioprojet shall be solely responsible for (A) the costs associated with the Development activities with respect to the Product for the Partner Territory as set forth in Section 4.2 of this Agreement) and (B) all costs associated with the Development, regulatory and Commercialization activities with respect to the Product for the Bioprojet Territory.
- (iii) Effective from and after the Effective Date through approval by the FDA of the first NDA in the name of Bioprojet, Partner shall have the right to actively participate and assist Bioprojet in its preparation and submission of the initial NDA to the FDA with respect to the Product for the Partner Territory, including in particular with respect (A) the preparation and submission of the NDA for the Product for Narcolepsy (both with and without Cataplexy),

- (B) interactions with the FDA regarding the same (including product label negotiations), (C) management of the Peripheral and Central Nervous System Drug Advisory Committee meeting, and (D) seeking FDA approval of the same.
- (iv) Effective from and after the Effective Date, Partner shall have the right to take the lead, with Bioprojet's assistance, with respect to (A) the opening of an IND in the Partner Territory to initiate an expanded access program ("<u>EAP</u>") in the name of Partner and interactions with the FDA regarding the same, and (B) all negotiations with the FDA regarding the Product's labeling.
- (b) Ownership of Regulatory Approvals. Partner or a Partner Affiliate shall hold, as licensee, all Regulatory Approvals (including, all Regulatory Filings and applications for NDAs) for the Product in the Field in the Partner Territory as Licensed Assets under this Agreement in trust for Bioprojet for the Term of this Agreement.

(c) Regulatory Activities and Cooperation.

- (i) The JSC shall approve the overall strategy and positioning of all material regulatory submissions and filings by Partner in the Partner Territory prior to their submission or filing, based upon reasonably detailed reports and summaries of such submissions and filings to be provided by Partner. In connection with such review, Partner shall provide to the JSC such additional information regarding a proposed material regulatory filing as either Party may reasonably request. After transfer of the initial NDA to Partner, Bioprojet shall have the right, but no obligation, to fully participate in all material meetings, conferences and discussions by Partner or its Affiliates with the FDA and other Regulatory Authorities pertaining to the Product, including without limitation having Bioprojet representatives present at such meetings, conferences or discussions. Partner shall provide Bioprojet with reasonable advance notice of all such meetings and other contact and advance copies of all related material documents and other relevant material information relating to such meetings or other contact.
- (ii) Partner shall provide to Bioprojet, as well as to the JSC, advance drafts of any material documents or other material correspondence pertaining to the Product NDA's or the Product, including any proposed labeling, that Partner plans to submit to the FDA or another Regulatory Authority in the Partner Territory. The JSC and/or Bioprojet may provide comments regarding such documents and other correspondence prior to their submission, which comments Partner shall consider in good faith. Partner shall provide Bioprojet with copies of all material regulatory submissions it makes to, and all material regulatory correspondence it receives from, the FDA or another Regulatory Authority in the Partner Territory pertaining to the Product NDA's or the Product in the Partner Territory. Notices, copies of regulatory submissions and correspondence, and other materials to be given in advance as provided in this Section 4.3(c) shall be provided at least five (5) business days in advance unless circumstances necessitate a shorter time period (i.e. three (3) day NDA Field alert reports, seven (7) day IND safety reports), and in any event not less than a reasonable time in advance under the circumstances.
- (iii) Bioprojet shall provide to Partner advance drafts of any material documents or other material correspondence pertaining to Product Regulatory Filings or the Product, including any proposed labeling, that Bioprojet plans to submit to any Regulatory

Authority in the European Union, to the extent that such Product Regulatory Filings may have an impact on the Commercialization of the Product in the Partner Territory. Partner may provide comments regarding such documents and other correspondence prior to their submission, which comments Bioprojet shall consider in good faith. Bioprojet shall provide Partner, as well as to the JSC, with copies of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to Product Regulatory Filings or the Product in the Field in the European Union.

- (d) Rights of Reference and Access to Data. Subject to Section 4.2(ii), each Party shall have the right (i) to cross-reference the other Party's Regulatory Filings and Regulatory Approvals related to the Product (including in the case of Partner, the right to cross-reference Bioprojet's, its Affiliate's or its subcontractor's drug master files for Product (collectively, "DMF")), and (ii) to access such Regulatory Filings and Regulatory Approvals and any Data therein and use such Data in connection with the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such Data in its own Regulatory Filings and Regulatory Approvals for Product in the Field in the Partner Territory with respect to Partner and in the Bioprojet Territory with respect to Bioprojet; provided, however, that the Parties expressly acknowledge and agree that, although clause (i) above grants Partner and its Affiliates and Sublicensees the right to cross-reference the DMF and the Data therein, clause (ii) above does not authorize Partner or its Affiliates or Sublicensees to access, or require Bioprojet to disclose, the closed portions of the DMF or the Data therein. Subject to Section 4.2(ii), each Party hereby grants to the other Party a "Right of Reference," as that term is defined in United States 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliate that relates to the Product for use by Partner to Commercialize the Product in the Field in the Partner Territory pursuant to this Agreement or by Bioprojet to Develop or Commercialize the Product in the Bioprojet Territory. Each Party or such Affiliate(s) thereof shall provide a signed statement to this effect, if requested by the other Party, in accordance with United States 21 C.F.R. § 314.50(g)(3) or its equivalent as required in any other country or region or otherwi
- (e) <u>Disclaimer</u>. Other than as expressly set forth in this Agreement, any Data disclosed by a Party to the other Party under this Agreement is provided on an "as is" basis, without any warranty (express or implied) of any kind, and the disclosing Party expressly disclaims all such warranties to the maximum extent permitted under applicable law. The receiving Party, on behalf of itself and its Affiliates and Sublicensees, accepts all risk and liability in relation to the use of the Data received from the disclosing Party under this Agreement.

4.4 Pharmacovigilance Responsibilities.

- (a) Prior to the transfer of the initial NDA to Partner:
- (i) Partner shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the EAP for the Product in the Partner Territory, including filing all reports required to be filed in order to maintain any Regulatory Approvals granted in connection with the EAP for the Product in the Partner Territory (including, reporting

of adverse events/adverse drug experiences, product quality complaints and safety data relating to the EAP for the Product in the Partner Territory). Partner shall promptly notify Bioprojet with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the EAP for the Product in the Partner Territory. Partner shall ensure that its Affiliates and Sublicensees comply with such reporting obligations; and

- (ii) Bioprojet shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the Product in the Partner Territory (other than the pharmacovigilance activities for which Partner is responsible pursuant to Section 4.4(a)(i)), including filing all reports required to be filed in order to maintain any Regulatory Approvals granted for the Product in the Partner Territory (including, reporting of adverse events/adverse drug experiences, product quality complaints and safety data relating to the Product in the Partner Territory). Bioprojet shall promptly notify Partner with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the Product, in the Partner Territory. Bioprojet shall ensure that its Affiliates and Sublicensees comply with such reporting obligations.
- (b) Effective from and after the transfer of the initial NDA to Partner, Partner shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the Product in the Partner Territory, including filing all reports required to be filed in order to maintain any Regulatory Approvals granted for the Product in the Partner Territory (including, reporting of adverse events/adverse drug experiences, product quality complaints and safety data relating to the Product in the Partner Territory). Partner shall promptly notify Bioprojet with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the Product, in the Partner Territory. Partner shall ensure that its Affiliates and Sublicensees comply with such reporting obligations. Partner will allow Bioprojet, upon reasonable notice and at its own expense, to perform quality system audits at its facility, including the review of applicable documentation up to two (2) times per Contract Year.
- (c) Bioprojet shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the Product in the Bioprojet Territory, including filing all reports required to be filed in order to maintain any Regulatory Approvals granted for the Product in the Bioprojet Territory (including, reporting of adverse events/adverse drug experiences, product quality complaints and safety data relating to the Product in the Bioprojet Territory). Bioprojet shall promptly notify Partner with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the Product in the Bioprojet Territory. Bioprojet shall ensure that its Affiliates and Third Party sublicensees comply with such reporting obligations. Bioprojet shall be responsible, at its sole cost and expense, for managing and maintaining the global core data safety sheet for the Product (the "Product Core Data Sheet") within and outside the Partner Territory; and Partner shall cooperate with and assist Bioprojet, as requested and/or as provided for in the Pharmacovigilance Agreement (as defined below), to enable Bioprojet to meet its regulatory reporting and other requirements with respect to managing and maintaining the Product Core Data Sheet within and outside the Partner Territory.
- (d) Within ninety (90) days of the Signing Date (or any other date agreed upon between the Parties), the Parties shall enter into a mutually agreed upon Pharmacovigilance Agreement, (the "Pharmacovigilance Agreement") and containing terms and provisions no less

stringent than those required by applicable ICH Guidelines, including: (i) providing detailed procedures regarding the management and maintenance of the Product Core Data Sheet and related information and the exchange of safety data relating to the Product within and outside the Partner Territory within appropriate time frames and in an appropriate format to enable each Party to meet its expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance by the applicable Party with the reporting requirements of all applicable Regulatory Authorities, and all applicable legal and regulatory requirements for the management of safety data, within and outside the Partner Territory.

- (e) Without limiting Sections 4.4(d) above, within a reasonable period of time following the Effective Date, each Party shall establish and thereafter maintain a safety database with respect to the Product in such Party's territory (i.e., in the case of Partner, the Partner Territory, and in the case of Bioprojet, the Bioprojet Territory), and shall provide the other Party with a duplicate copy of such safety database. The Pharmacovigilance Agreement shall include provisions to facilitate and ensure that each Party has sufficient information to maintain its own safety database thereafter.
- 4.5 Medical Affairs Responsibilities. Effective from and after the Effective Date, Partner shall be responsible, at its sole cost and expense, for all medical affairs activities with respect to the Product in the Partner Territory, including (a) developing and implementing a medical affairs strategy (including a strategy and action plan to develop broad based key-opinion-leader ("KOL") support) with respect to the Product in the Partner Territory for the pre-Regulatory Approval and post-Regulatory Approval periods and (b) engaging (either directly as employees or indirectly as independent contractors or consultants) at least (i) five (5) full time equivalents within forty-five (45) calendar days after the Effective Date and (ii) twelve (12) medical science liaisons or other medical affairs personnel no later than thirty (30) calendar days prior to the anticipated Regulatory Approval by the FDA of the first Product NDA in the Partner Territory, in each case with respect to such medical affairs strategy.
- 4.6 Compliance with the Laws. Each Party shall comply in all material respects with all, and shall not violate in any material respect any, applicable laws with respect to the conduct of its respective business or the ownership or operation of its respective properties or assets, including the following laws, as applicable: (i) the laws composing the Medicare and Medicaid Programs, including applicable provisions of the Social Security Act (e.g., Civil Monetary Penalties Act, 42 U.S.C. § 1320a-7a, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b), (ii) (x) any other laws prohibiting rebates, kickbacks, fee-splitting or other financial incentives or inducements, including providing products or services below cost for the referral or continuation of business, and (y) the False Claims Act, 31 U.S.C. § 3729 et seq., and (iii) laws enforced by the FDA, including the FDCA and Section 21 of the C.F.R. Each Party shall comply with Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation.

COMMERCIALIZATION AND PROMOTION

5.1 Partner Commercialization.

(a) <u>Partner's Responsibility</u>. Except as provided below, effective from and after the Effective Date, Partner shall be responsible for, and shall control the conduct of, the Commercialization of the Product in the Partner Territory, at its expense, under and in material accordance with the then-current Commercialization Plan.

(b) Commercialization Plan.

- (i) The initial plan for the Commercialization of the Product in the Field in the Partner Territory is attached to this Agreement as Exhibit 5.1 (the "Initial Commercialization Plan"), and includes in reasonable detail: the number of sales representatives to be deployed, an account/physician target-specific detail and coverage plan (including, "call points"), the dollar amount and allocation of planned promotional and marketing expenses, the projected dates for the First Commercial Sale of the Product in the Partner Territory, as well as an outline regarding the price and brand positioning of the Product, which shall be consistent with the minimum commercial diligences set forth in Section 5.2(b). The Initial Commercialization Plan can be adjusted by the JSC.
- (ii) Partner shall prepare for the JSC's review updates of the Commercialization Plan on an ongoing basis, and in any event, the JSC shall review the then-current Commercialization Plan in the sixth (6th) and twelfth (12th) month of each calendar year.
- (iii) Partner shall carry out and manage, and shall cause its Affiliates and Sublicensees to carry out and manage, the Commercialization of the Product in the Partner Territory in material accordance with the then-current Commercialization Plan and the provisions of this Agreement.
- (iv) If, after taking into account all potential opportunities with respect to the Product in a comprehensive analysis of the relevant clinical science, clinical need, published data and commercial considerations, the JSC determines that Partner should develop and present to Bioprojet a go-to-market Commercialization plan for the OSA Target Indication (the "OSA Proposal"), then Partner shall do so within ninety (90) days of such determination. The OSA Proposal shall take into account the Parties' mutual agreement that the Product's optimal brand positioning and pricing strategy in the Partner Territory are the Narcolepsy with Cataplexy and EDS Target Indications and include, among other things, (i) analysis of potential regulatory options for the Product in the Partner Territory for the Narcolepsy with Cataplexy, EDT and OSA Target Indications, including an assessment of the viability of different brand names, and simultaneous Commercialization of the same compound, for such three (3) Target Indications, (ii) commercial payor/pricing analysis for potential managed care contracting strategies for the OSA Target Indication and (iii) a full medical affairs development program to support the OSA Target Indication. The Parties shall discuss the OSA Proposal in good faith and, if the Parties

mutually agree upon a go-to-market Commercialization plan for the OSA Target Indications (whether incorporating, in whole or in part, the elements of the OSA Proposal or otherwise), the Initial Commercialization Plan shall be amended by mutual written agreement of the Parties to reflect such mutually agreed upon go-to-market Commercialization plan.

5.2 <u>Diligence</u>.

- (a) Partner shall be responsible for launching the Product in the Partner Territory with respect to the Target Indication(s) as soon as practical but no later than within **two (2)]** months following approval of the applicable Product NDA in the Partner Territory (or as soon as practicable thereafter in light of sufficient Product supply in applicable trade dress), and Partner shall use commercially reasonable efforts to Commercialize the Product in the Field in the Partner Territory.
- (b) Without limiting Partner's diligence obligation as set forth in Section 5.2(a), the Initial Commercialization Plan shall provide that Partner shall, with respect to the Target Indications, (i) deploy on the date of Regulatory Approval by the FDA of the first Product NDA approximately the number of sales representatives as indicated in the Initial Commercialization Plan in Exhibit 5.1, in connection with Commercialization of the Product in the Partner Territory, and (ii) spend the amounts set forth in the Initial Commercialization Plan, which consists of [***] (the "Commercialization Expenditures") to prepare and launch the Product in the Target Indications, on Partner employees and other infrastructure and promotional, advertising, educational and marketing activities, and medical affairs for the Product in the Partner Territory (but excluding, for the avoidance of doubt, any payment to be made to Bioprojet hereunder). The Commercialization Expenditures shall be made over the course of three (3) years from submission of the Regulatory Approval or other timing agreed upon between the Parties.
- 5.3 Marketing Materials. Marketing, advertising and promotional materials (the "Marketing Materials") concerning the Product for use in the Partner Territory, as well as training manuals and education and communication materials (the "Educational Materials") for Sales Representatives in the Partner Territory shall be developed and prepared by Partner, at its own expense. Any Marketing Materials, training manuals and/or Educational Materials developed and used by Partner, its Affiliates and Sublicensees for the Product in the Partner Territory shall be consistent with the Regulatory Approval therein and the Commercialization Plan and shall comply with all applicable laws, rules and regulations. Partner shall keep Bioprojet reasonably informed with respect to Marketing Materials and Educational Materials and shall provide to Bioprojet copies (in electronic form) of any new Marketing Materials and/or Educational Materials, and take into account Bioprojet's reasonable comments, including with respect to the compliance with Bioprojet's worldwide Product profile and this Section 5.3. It is agreed that each Party shall have the right to use any Marketing Materials and Educational Materials developed by the other Party for Commercialization of the Product in the Field in its own territory.

PAYMENTS

- **6.1** <u>License Fee.</u> Partner shall pay to Bioprojet a one-time initial license royalty fee (the "<u>Initial Payment</u>") in an amount of One Hundred Fifty Million (\$150,000,000) USD within five (5) calendar days following the Effective Date in accordance with the payment provisions of Article 7. Prior to the Signing Date, in guarantee of the payment of such upfront amount, Partner has made a cash deposit for the total amount of the Initial Payment in an escrow account at a bank mutually acceptable to the Parties, pursuant to a mutually agreed upon escrow agreement executed by the Parties (the "**Escrow Agreement**"). Such escrow agreement shall provide, *inter alia*, that this cash deposit will be paid to Bioprojet upon the Closing as a credit against the Initial Payment or otherwise released from escrow, in each case under the terms and subject to the conditions provided for in said escrow agreement. Except as set forth in this Section 6.1 and said escrow agreement, the Initial Payment shall not be refundable or creditable against any future milestone, royalties or other payments by Partner to Bioprojet under this Agreement.
 - **6.2** <u>Milestone Payments</u>. In addition, Partner shall pay to Bioprojet additional milestone payments as follows:
- (a) a one-time, non-creditable, non-refundable payment in an amount of Fifty Million (\$50,000,000) USD upon the first NDA acceptance by the FDA with respect to the Product in the Field;
- (b) the applicable one-time, non-creditable, non-refundable payment upon NDA approval by the FDA with respect to the Product, in the following amount with respect to the corresponding approved label indication under one of the two scenarios described below:

	Scenario A			
	Milestone Event	Milestone Payment		
1	NDA approval by the FDA for indications of Narcolepsy including treatment of Cataplexy and EDS (or specifically stated as Type 1 and Type 2 Narcolepsy)	One Hundred and Fifty Million (\$150,000,000) USD		
AND				
2	Product is not subject to any controlled substance scheduling or is designated as Schedule IV scheduling with the Drug Enforcement Agency ("DEA") or any other Governmental Authority at the time of NDA approval by the FDA, or on the subsequent date of First Commercial Sale if the DEA has not made a scheduling decision by the date of NDA approval by the FDA	Twenty-Five Million (\$25,000,000) USD		
OD				

OR

	Scenario B			
	Milestone Event	Milestone Payment		
1	NDA approval by the FDA for an indication of EDS only (without any indication of Narcolepsy or without any indication of Narcolepsy specifically including treatment of Cataplexy or specifically formulated as Type 2 Narcolepsy only)	Fifty Million (\$50,000,000) USD		
AND				
2	Product is not subject to any controlled substance scheduling or is designated as Schedule IV scheduling with the DEA or any other Governmental Authority at the time of NDA approval by the FDA, or on the subsequent date of First Commercial Sale if the DEA has not made a scheduling decision by the date of NDA approval by the FDA	Twenty-Five Million (\$25,000,000) USD		
AND				
3	NDA approval by the FDA for a subsequent indication of Narcolepsy including treatment of Cataplexy is obtained, in the event the initial NDA approval by the FDA was solely for an indication of EDS (without any indication of Narcolepsy or without any indication of Narcolepsy specifically including treatment of Cataplexy or specifically formulated as Type 2 Narcolepsy only) as described in subsection 1 above	One Hundred Million (\$100,000,000) USD		

For the avoidance of doubt, Scenario A and Scenario B are mutually exclusive, with the result that if a payment is made by Partner under subsection 1 of Scenario A above, then no payment shall ever become due under subsections 1, 2 or 3 of Scenario B and *vice versa*.

- (c) Upon attainment of aggregate Net Sales of the Product in the Partner Territory of at least Five Hundred Million (\$500,000,000) USD subsequent to the date of NDA approval by the FDA, Partner shall pay to Bioprojet a one-time, non-creditable, non-refundable payment in an amount of Forty Million (\$40,000,000) USD.
- (d) Partner shall notify Bioprojet in writing after the first achievement by Partner, or any of its Affiliates or Sublicensees, of each milestone set out in this Section 6.2 promptly, but in no event more than five (5) calendar days thereafter, and pay any corresponding milestone payment within fifteen (15) days of such achievement.

6.3 Royalty Payments.

(a) Following the First Commercial Sale of Product during the Royalty Term, Partner shall, pay to Bioprojet tiered royalties on Annual Net Sales of the Product in the Partner Territory ("Royalty Payments") as set forth in the table below:

Annual Net Sales	Royalty Rate (% of Annual Net Sales)
Portion of Such Annual Net Sales less than or equal to	
US\$200,000,000	13%
Portion of Such Annual Net Sales greater than US\$200,000,000 and	
less than or equal to US\$400,000,000	15%
Portion of Such Annual Net Sales greater than US\$400,000,000 and	
less than US\$600,000,000	21%
Portion of Such Annual Net Sales greater than US\$600,000,000	24%

- (b) In addition to the Royalty Payment and in consideration for the Trademark License, following the First Commercial Sale of Product and for twenty (20) years thereafter, Partner shall, pay to Bioprojet royalties on Annual Net Sales of the Product in the Partner Territory at a rate equal to three percent (3%) ("Trademark Royalty Payments").
- **6.4** Royalty Payments. Partner shall make Royalty Payments and the Trademark Royalty Payments to Bioprojet on a Calendar Quarter basis, no later than forty-five (45) days after the expiration of such Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale occurs, and subject to the minimum royalty payments due under Section 6.6, if any. Each such payment shall be accompanied by a report stating (i) the number of units of Product sold by Partner, its Affiliates and Sublicensees during such Calendar Quarter; (ii) Partner's calculation of Net Sales during such Calendar Quarter; and (iii) amounts owed to Bioprojet under Section 0 for such Calendar Quarter (each such report, a "Royalty Report"). For clarity, Partner shall have no obligation to make any Royalty Payment under this Agreement with respect to Annual Net Sales of Product after the Royalty Term has expired. Upon expiration of the Royalty Term with respect to the Product in the Partner Territory, the license grants to Partner under Section 2.1 above with respect to the Product in the Partner Territory shall become non-exclusive, perpetual, fully-paid and non-assessable and non-royalty bearing except for the Trademark Royalty Payment. With respect to any given Calendar Quarter, Partner shall pay one third (1/3) of the amounts owed to Bioprojet under this Section 6.3(a) for such Calendar Quarter to Bioprojet Europe Limited.
- **6.5** Royalty Rate Reduction for Licenses of Third Party Patent Rights. If, in the reasonable opinion of Partner, the Commercialization of the Product in the Partner Territory by Partner or its Affiliates or Sublicensees infringes or is reasonably expected to infringe any Patent of a Third Party in the Partner Territory (such right, a "Third Party Patent Right"), then, as between

the Parties, Partner shall have the right, but not the obligation, to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for Partner or its Affiliates or Sublicensees to Commercialize the Product in the Partner Territory; provided that, except as set forth below, as between the Parties, Partner shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such license. If the Parties agree that the Commercialization of the Product in the Partner Territory by Partner or its Affiliates or Sublicensees infringes or is reasonably expected to infringe any Third Party Patent Right, and Partner enters into an agreement with a Third Party in order to obtain a license to a Third Party Patent Right with respect to the Product that is reasonably necessary to Commercialize the Product in the Partner Territory, Partner shall be entitled to deduct from the Royalty Payments payable to Bioprojet under Section 6.3(a) in a given Calendar Quarter with respect to the Product fifty percent (50%) of the royalties paid to such Third Party in such Calendar Quarter under such agreement, solely to the extent that such royalties are triggered by sale of the Product. For clarity, to the extent the adjustments under this Section 6.5 cover periods in which payments are due based on more than one royalty rate described in Section 6.3(a) for the Product, the Annual Net Sales to which such adjustments apply shall be distributed on a pro rata basis among the applicable royalty rates for the Product set forth in Section 6.3(a) above.

6.6 Minimum Royalties. If and when an NDA approval is granted by the FDA for the Product in the indications of narcolepsy including treatment of cataplexy and EDS (or specifically stated as Type 1 and Type 2 narcolepsy), Partner shall, beginning in the third Contract Year and continuing for the Royalty Term, pay Bioprojet the following minimum royalties ("Minimum Royalties") to the extent they exceed the sum of the royalties paid or payable to Bioprojet by Partner pursuant to Section 6.3. Such Minimum Royalties shall be calculated on an annual basis and paid to Bioprojet within forty-five (45) calendar days following the end of the applicable Contract Year.

Contract Year	Minim (in	num Royalty Millions)
1		—
2		
3	\$	11.6M
4	\$	14.5M
5	\$	17.4M
6	\$	20.3M
7	\$	23.3M
8	\$	26.1M
9	\$	29.1M
10	\$	32.0M

For the sake of clarity, for example, if the royalty payment due to Bioprojet, as calculated using the formula set forth in Section 6.3, is US\$16.0 million in Contract Year 5 (2022), then Partner shall pay Bioprojet an additional US\$1.4 million to ensure the Minimum Royalty payment amount for that year.

PAYMENTS; BOOKS AND RECORDS

- 7.1 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. Any payments or portions thereof due under this Agreement that are not paid within thirty (30) calendar days after the date such payments are due under this Agreement shall bear interest at an annualized rate equal to the US dollar Libor interest rate at one month plus three (3) percentage point, calculated on the number of calendar days such payment is delinquent, compounded monthly and computed on the basis of a three hundred sixty five (365) day year, unless validly disputed. This Section 7.1 shall in no way limit any other remedies available to the Parties.
- 7.2 <u>Currency Conversion</u>. Unless otherwise expressly stated in this Agreement, all amounts specified in this Agreement are in USD, and all payments by one Party to the other Party under this Agreement shall be paid in USD. If any currency conversion shall be required in connection with the payment of royalties or other amounts under this Agreement, such conversion shall be calculated using the average exchange rate for the conversion of foreign currency into USD, quoted by the Wall Street Journal for each business day of the Calendar Quarter to which such payment pertains.

7.3 <u>Taxes</u>.

- (a) Withholding Taxes. If applicable laws or regulations require withholding by Partner of any taxes imposed upon Bioprojet on account of any royalties or other payments paid under this Agreement, such taxes shall be deducted by Partner as required by applicable law from such payment and shall be paid by Partner to the proper taxing authorities. Official receipts of payment of any withholding tax shall be secured and sent to Bioprojet as evidence of such payment. The Parties shall exercise their reasonable efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any applicable tax treaty, and shall cooperate in filing any forms required for such reduction. All payments hereunder shall be made by Partner from an entity resident in the United States or the European Union.
- (b) <u>Sales Taxes</u>. Any U.S. sales taxes (including any consumption tax or value added tax), use tax, transfer taxes, duties or similar governmental charges required to be paid in connection with any payments by Partner to Bioprojet hereunder shall be the sole responsibility of Partner. In the event that Bioprojet is required to pay any such amounts, Partner shall promptly remit payment to Bioprojet of such amounts. All foreign sales taxes, duties or similar governmental charges required in connection with any payments by Partner to Bioprojet hereunder shall be the sole responsibility of Bioprojet. In the event that Partner is required to pay any such amounts, Bioprojet shall promptly remit payment to Partner of such amounts.
- **7.4** Records; Inspection. Partner shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to Bioprojet pursuant to this Agreement. Such books and records shall be kept for at least three (3) years following the end of the Calendar Quarter to which they pertain.

Such records will be open for inspection by an independent auditor chosen by Bioprojet and reasonably acceptable to Partner for the purpose of verifying the amounts payable by Partner hereunder. Such inspections may be made no more than once each calendar year, at reasonable times and on reasonable prior written notice. Such records for any particular Calendar Quarter shall be subject to no more than one inspection. The independent auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.4 shall be at the expense of Bioprojet, unless a variation or error producing an underpayment in amounts payable exceeding five percent (5%) of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by Partner, together with interest on such unpaid amounts at the rate set forth in Section 7.1 above.

Article 8

CERTAIN COVENANTS

- **8.1** Commercially Reasonable Efforts of Partner. From and after the approval of the first NDA by the FDA, Partner shall use commercially reasonable and legally compliant efforts to maintain NDA approval, launch the Product in the Partner Territory and maximize the sales potential of the Product in the Partner Territory in a prompt and expeditious manner.
- **8.2** <u>General Communications.</u> Partner shall keep Bioprojet reasonably informed as to its progress and activities relating to the Commercialization of the Product for the Partner Territory, including with respect to regulatory matters and meetings with Regulatory Authorities, by way of updates to the JSC at its meetings and as otherwise specified in this Agreement, or as reasonably requested by Bioprojet at any other time. In order to facilitate the Parties' exercise of their rights and fulfillment of their obligations hereunder, each Party agrees to give due consideration to any comments provided by the other Party with respect to such Commercialization of the Product for the Partner Territory.
- **8.3** Exclusivity of Efforts. During the Term of this Agreement, Partner agrees that Partner shall not, and shall cause its Affiliates not to, directly or indirectly, develop, market, sell, promote, or file an NDA with respect to, any Field Products in the Partner Territory.

Article 9

PRODUCT SUPPLY AND DISTRIBUTION

9.1 Product Supply. Within ninety (90) days of the Signing Date, the Parties shall enter into a mutually agreed upon Supply Agreement (the "Supply Agreement") whereby Bioprojet shall supply Partner with all of Partner's, its Affiliates' and Sublicensees' requirements for the Product for the Partner Territory during the Term of this Agreement. Key terms of the Supply Agreement are set forth in Exhibit 9.1. All Product requirements during the term of the Supply Agreement, of Partner, its Affiliates and Sublicensees shall be purchased by Partner from Bioprojet. The transfer price for the Product shall be equal to Bioprojet Cost of Good plus [***] in accordance with generally accepted accounting principles.

9.2 Suppliers. Without limiting Bioprojet's responsibility under this Agreement, Bioprojet shall have the right at any time to satisfy its supply obligations to Partner hereunder either in whole or in part through arrangements with Third Parties engaged to perform services or supply facilities or goods in connection with the manufacture, testing, and/or packaging of Product; provided that Bioprojet shall remain responsible for such activities to the same extent as if Bioprojet had performed such activities itself. Bioprojet shall give Partner prior written notice of any such arrangement to the extent that such arrangement would require changes to an NDA filed, or a Regulatory Approval obtained, in the Partner Territory and such notice shall be provided sufficiently in advance to permit Partner to effect such change to the applicable NDAs or Regulatory Approvals.

9.3 Shortage of Supply.

- (a) <u>Cooperation</u>. Bioprojet and Partner shall cooperate, in particular by the exchange of information within the JSC, to establish reasonable plans and procedures to avoid any shortage of supply of Product or API, as applicable.
- (b) <u>Procedures</u>. If at any time Bioprojet becomes unable, or concludes that it will be unable, to supply Partner's requirements for the Product or API, Bioprojet shall immediately notify Partner in writing. In such event, the Parties shall immediately convene to address the problem, including locating alternative suppliers and facilities to increase production and identifying other actions necessary to resolve the problem. Based on such interactions, the Parties shall reasonably agree on appropriate measures to remedy the shortage and shall promptly implement such measures. In any event, both Parties agree to respond with the level of speed and diligence commensurate with the severity of the problem. In no event shall Partner's cost of any alternative supply of the Product exceed the cost paid by Partners pursuant to the Supply Agreement, with Bioprojet being finally responsible for any excess.
- (c) <u>Allocation</u>. If despite the foregoing measures Bioprojet is unable to supply Partner's requirements of Product or API, as applicable, Bioprojet shall allocate the quantities of the Product or API that Bioprojet has in inventory, and that Bioprojet is able to produce, on a reasonable worldwide basis (based upon sales history and realistic forecasted demand).
- (d) <u>Limitation of Remedies</u>. Except for failures caused by Bioprojet's gross negligence or intentional refusal to supply available quantities of the Product, Bioprojet shall not be liable to Partner or any of its Affiliates or Sublicensees for special, incidental, indirect, consequential or other monetary damages (including lost profits) under this Article 9.
- (e) <u>Direct Agreements</u>. Partner shall use commercially reasonable efforts to enter into, and Bioprojet shall use commercially reasonable efforts to facilitate Partner's entry into, direct agreements with the Bioprojet's current API and Product suppliers (the "<u>Current CMOs</u>"), for the supply of the API and Product on substantially the same terms and conditions as those applied to Bioprojet under its supply agreement with the applicable Bioprojet CMO as of the Effective Date (the "<u>Existing Agreements</u>"). If after a period of eighteen (18) months from the Effective Date or any reasonable period agreed upon between the Parties, Partner has not entered into direct agreements with the Current CMOs, at Bioprojet's request, Bioprojet shall assign and Partner shall assume, Bioprojet's rights and obligations under one or more of the Existing

Agreements as requested by Bioprojet. In such case, Bioprojet will be released from any and all obligations to Partner hereunder with respect to the supply activities covered by the above direct agreement and/or assigned Existing Agreement and the portion of the Supply Agreements corresponding to such activities will be terminated accordingly.

Article 10

CONFIDENTIALITY

- 10.1 <u>Confidential Information</u>. Except as expressly provided in this Agreement, the Parties agree that the receiving Party shall not publish or otherwise disclose, and shall not use for any purpose, any information furnished to it by the other Party hereto pursuant to this Agreement (collectively, "<u>Confidential Information</u>"), without the prior written consent of the disclosing Party. Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by written documentation:
- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure or, was developed by the receiving Party independent of disclosure by the disclosing Party;
 - (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) was subsequently lawfully disclosed to the receiving Party on a non-confidential basis by a person other than the disclosing Party, and who did not directly or indirectly receive such information from disclosing Party; or
 - (e) is developed by the receiving Party without use of or reference to any information or materials disclosed by the disclosing Party.
- 10.2 Permitted Disclosures. Notwithstanding the provisions of Section 10.1 above and subject to Sections 10.3 and 10.4 below, a receiving Party hereto may disclose the disclosing Party's Confidential Information to its Affiliates, licensees (with respect to Bioprojet), permitted Sublicensees (with respect to Partner) and any other Third Parties to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement, prosecuting or defending litigation, complying with applicable laws or regulations or the rules of any public stock exchange, submitting information to tax or other Governmental Authorities. If a receiving Party is required by applicable laws or regulations to make any such disclosure of the disclosing Party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the disclosing Party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, shall use diligent efforts to secure confidential treatment of such Confidential Information of the disclosing Party prior to its disclosure (whether through protective orders or otherwise). For any other disclosures of the other Party's Confidential Information, including to Affiliates, licensees (with respect to Bioprojet),

permitted Sublicensees (with respect to Partner) and other Third Parties, a Party shall ensure that the recipient thereof is bound by a written confidentiality agreement as materially protective of such Confidential Information and the disclosing Party as this Article 10. For clarity, it is understood that Bioprojet may use and disclose, in accordance with the foregoing, any Partner Know-How provided to Bioprojet by Partner in connection with the development, Commercialization, marketing, promotion and/or distribution of the Product for the Bioprojet Territory.

- 10.3 Confidentiality of Agreement Terms. Each Party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement: (a) to advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners or private investors, and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement; or (b) to the extent necessary to comply with applicable laws and court orders, including applicable securities laws, regulations or guidances; provided that in the case of paragraph (b) the disclosing Party shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with applicable securities laws, regulations or guidances) allow the other Party a reasonable opportunity to oppose with the body initiating the process and, to the extent allowable by applicable law, to seek limitations on the portion of the Agreement that is required to be disclosed.
- 10.4 Publication of Clinical Data. Prior to publishing, publicly presenting and/or submitting for written or oral publication a manuscript, abstract or the like that includes Data from Clinical Studies with respect to the Product that has not previously published pursuant to this Section 10.4, Partner shall provide Bioprojet a copy thereof for its review and approval for at least thirty (30) calendar days (unless Partner is required by applicable law to publish such information sooner). Partner shall consider in good faith any comments provided by Bioprojet during such thirty (30) day period. In addition, Partner shall, at the request of Bioprojet, remove any Confidential Information of Bioprojet therefrom, except Partner shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety of the Product that Partner believes in good faith it is obligated or appropriate to disclose.
- the other, prior to submission for publication, of a draft of any articles and papers containing Confidential Information or concerning the Product which have been prepared by or on behalf of such Party in the Field (each a "Scientific Paper") to be published in indexed medical and scientific journals and similar publications ("Medical Journals"). Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have fifteen (15) business days to notify the sending Party of its observations and suggestions with respect thereto (it being understood that, during such fifteen (15)-Business Day period, no submission for publication thereof shall take place) and the Parties shall discuss these observations and suggestions. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any Patent. Neither Party will publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical

Journal, within ten (10) business days after the approval thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines).

- 10.6 Abstracts and Posters. If a Party intends to present findings with respect to the Product in the Field at symposia or other meetings of healthcare professionals, or international and/or US or European congresses, conferences or meetings organized by a professional society or organization (any such occasion, a "Scientific Meeting"), to the extent permitted by applicable laws, such Party through the JSC or its designee shall provide to the other, prior to submission or presentation, as the case may be, copies of (i) all abstracts that will be submitted for publication in connection with (a) any international Scientific Meeting, in any Scientific Meeting in the European Union or in the United States and, (b) with respect to Partner, any Scientific Meeting within or without the Partner Territory and (c) with respect to Bioprojet, any Scientific Meeting in the Partner Territory and in the European Union and (ii) all posters that will be presented at such Scientific Meeting, in each case, concerning the Product which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster the receiving Party shall have five (5) business days in the case of an abstract, or ten (10) business days in the case of a poster, to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such review period, as applicable, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of (i) all final abstracts as soon as reasonably practicable after the approval of the Scientific Meeting, and (ii) all final posters accepted for publication or to be presented five (5) business days prior to the planned publication or presentation thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). The Parties shall use good faith and commercially reasonable efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.
 - 10.7 Press Releases. No Party will release a press release without the prior written approval of the other Party.
- 10.8 <u>Prior Non-Disclosure Agreements</u>. Upon execution of this Agreement, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

Article 11

PATENT PROSECUTION AND ENFORCEMENT

11.1 Ownership of Inventions. Title to all inventions and other intellectual property made solely by Partner personnel or independent contractors (or that of any Affiliate) in connection

with this Agreement shall be owned by Partner (or its respective Affiliate). Title to all inventions and other intellectual property made solely by Bioprojet personnel in connection with this Agreement shall be owned by Bioprojet. Title to all inventions and other intellectual property made jointly by personnel of Bioprojet and Partner in connection with this Agreement shall be jointly owned by Bioprojet and Partner. Prosecution of any Patent with respect to such jointly-owned inventions and intellectual property shall be solely as mutually agreed. Except to the extent any such jointly-owned inventions or intellectual property for its own internal purposes, and neither Party shall have the right to enforce, license, or assign such jointly-owned inventions or intellectual property, without the prior written consent of the other Party. Partner hereby grants to Bioprojet a non-exclusive, worldwide, irrevocable, royalty-free license, with the right to sublicense, under any Improvements to make, have made, use, sell, offer for sale, import, practice and otherwise exploit the same, subject to the exclusive rights granted to Partner under this Agreement with respect to the Product in the Partner Territory. As used herein, "Improvements" means any Patent, invention or other intellectual property made by or under authority of Partner (including any Partner Know-How) using, or in connection with the manufacturing, use and/or Commercialization the Product, in each case, to the extent the same is owned or Controlled by Partner or any of its Affiliates or Sublicensees.

11.2 <u>Prosecution and Maintenance of Bioprojet Patents</u>.

- (a) <u>Prosecution</u>. As between Partner and Bioprojet, Bioprojet shall, at its expense, have responsibility for the filing, prosecution and maintenance of all Bioprojet Patents in the Partner Territory. Bioprojet agrees to keep Partner generally informed of the course of patent prosecution or other proceedings with respect to the Bioprojet Patents within the Partner Territory. Partner shall hold all information disclosed to it under this Section 11.2 as confidential.
- (b) <u>Patent Term Extensions</u>. Bioprojet shall have the right with respect to the Bioprojet Patents, and Partner shall have the right with respect to any Patents owned or Controlled by Partner, or its Affiliates or Sublicensees, related to the Product, to file all applications and take actions necessary to obtain patent term extensions, or similar additional or supplemental protection, with respect to the Product under statutes in the Partner Territory, which extensions shall be owned by the Party that owns or Controls the underlying Patent. If such Party declines to pursue such patent term extensions, then the other Party shall have the right on behalf of such Party to file all such applications and take all such actions necessary to obtain such patent term extensions (or similar additional or supplemental protection) with respect to the Product. In each case, the Parties shall fully cooperate to obtain such extensions and additional protection.

11.3 Enforcement.

(a) <u>Enforcement Actions</u>. In the event that Bioprojet or Partner becomes aware of actual or threatened infringement or misappropriation of any Bioprojet Patent or Bioprojet Know-How in the Partner Territory by the manufacture or sale or use of an unauthorized version of the Product ("<u>Infringing Product</u>"), that Party shall promptly notify the other Party in writing. Partner shall have the first right, but not the obligation, to initiate proceedings or take other appropriate action, at its own expense, against any such Third Party. If Partner does not initiate

proceedings or take other appropriate action within ninety (90) calendar days of receipt of a request by Bioprojet to initiate an enforcement proceeding, then Bioprojet shall be entitled to initiate infringement proceedings or take other appropriate action against an Infringing Product at its own expense and to include Partner as a nominal party plaintiff. The Party conducting such action shall have full control over its conduct, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In any event, the Parties shall assist one another and cooperate in any such litigation at the other's reasonable request.

(b) Recovery. Bioprojet and Partner shall recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof, associated with any litigation against infringers undertaken pursuant to Section 11.3 above or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated between Partner and Bioprojet as set forth in the following table to the extent such recovery represents damages relative to sales of Infringing Product in the Partner Territory:

Aggregate Recovery Amount in Excess of Out-of-Pocket Expenses	Percentage Payable to Bioprojet	Percentage Payable to Partner
Portion of such recovery less than or equal to US\$200,000,000	13%	87%
Portion of such recovery greater than US\$200,000,000 and less than or		
equal to US\$400,000,000	15%	85%
Portion of such recovery greater than US\$400,000,000 and less than		
US\$600,000,000	21%	79%
Portion of such recovery greater than US\$600,000,000	24%	76%

- (c) <u>Cooperation</u>. The Parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning the Bioprojet Patents or the Bioprojet Know-How within the Partner Territory and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party).
- 11.4 Third Party Infringement Claims. If the production, sale or use of the any Product in the Partner Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent infringement against Bioprojet or Partner (or their respective Affiliates, licensees or Sublicensees) (collectively, "Infringement Actions"), such Party shall promptly notify the other Party hereto in writing. The Party subject to such Infringement Action shall have the right to direct and control the defense thereof, at its own expense with counsel of its choice; provided, however, that the other Party may participate in the defense and/or settlement thereof, at its own expense

with counsel of its choice. In any event, the Party that is subject to the Infringement Action agrees to keep the other Party hereto reasonably informed of all material developments in connection with any such Infringement Action. Partner agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect the Product or the manufacture, use or sale of the Product within or outside the Partner Territory, without the prior written consent of Bioprojet, which shall not be unreasonably withheld, conditioned or delayed; and Bioprojet agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect the Product, or the packaging, use or sale of the Product, within the Partner Territory, without the prior written consent of Partner, which shall not be unreasonably withheld, conditioned or delayed.

11.5 Patent Marking. Partner agrees to mark, and have its Affiliates and Sublicensees mark, all patented Products they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the Partner Territory.

Article 12

TRADEMARKS

12.1 Display.

- (a) Except as set forth in this Section 12.1, all packaging materials, labels and Marketing Materials for the Product shall display the Product Trademarks, as listed in Exhibit 1.40, and no other product-specific trademarks or branding. Where possible, Partner shall utilize the mark "WAKIX" as the Product Trademark, or any other registered trademark designated as such by Bioprojet. If "WAKIX" cannot be used for legal, regulatory or other material reasons outside the Parties' reasonable control, in the Partner Territory, Partner shall utilize the alternative registered trademark, chosen by Bioprojet as the Product Trademark. If neither "WAKIX" or the alternative Product Trademark can be used for legal, regulatory or other material reasons outside the Parties' reasonable control, in the Partner Territory, the Parties will agree as to another Product Trademark to be filed and maintained by Bioprojet for use in the Partner Territory.
- (b) The Product shall be sold in the Partner Territory under the trade name of Partner; provided, however that to the extent permissible under applicable law within the Partner Territory, such packaging materials, labels and Marketing Materials shall also display the trade name of Bioprojet in reasonable size and prominence, as reasonably approved by Bioprojet. The trademarks of Partner, trade dress, style of packaging and the like with respect to the Product in the Partner Territory may be determined by Partner in a manner that is consistent with Partner's standard trade dress and style, but shall be subject to the approval by the JSC.
- **12.2** <u>Grant of License</u>. Bioprojet hereby grants to Partner an exclusive license to use the Product Trademarks and Bioprojet's trade name in the Partner Territory for the marketing, sale and promotion of the Product in accordance with this Agreement (the "<u>Trademark License</u>"), which Trademark License shall be reiterated pursuant to a separate agreement within ninety (90) days of the Effective Date. The ownership and all goodwill from the use of the Product Trademarks and Bioprojet's trade name shall vest in and inure to the exclusive benefit of Bioprojet.

- **12.3** Registration of Trade Marks. Bioprojet (or its designee) shall be responsible for filing and registering at Bioprojet's expense and in its own name (to the extent permitted by applicable law), appropriate registrations for such Product Trademarks in the Partner Territory.
- 12.4 Recordation of Licenses. If trade mark licenses must be recorded in the Partner Territory, Bioprojet will provide to Partner, on Partner's written request, a separate trademark license for the Product Trademarks and Partner will arrange for the recordation of such trade mark license with the appropriate governmental agency, at Partner's expense, promptly following receipt of such license from Bioprojet. Partner shall cooperate in the preparation and execution of such document(s).
- 12.5 <u>Approval of Packaging and Promotional Materials</u>. Without limiting Section 5.3 above, to preserve Bioprojet's legal rights in the Product Trademarks, Partner shall submit representative Marketing Materials, packaging and Product displaying the Product Trademarks and/or Bioprojet's trade name to Bioprojet for Bioprojet's review and approval prior to the first use of such Marketing Materials, packaging or Product and prior to any subsequent change or addition to such Marketing Materials, packaging or Product; provided that if Bioprojet has not responded within thirty (30) calendar days after the submission of such Marketing Materials, packaging or Product, Bioprojet's approval will be deemed to have been received.

12.6 Enforcement.

- (a) If either Party becomes aware of any actual or threatened infringement of any Product Trademark in the Partner Territory, such Party shall promptly notify the other Party in writing.
- (b) Partner shall have the first right, at its own expense, to initiate infringement proceedings or take other appropriate actions against an infringement of any Product Trademark in the Partner Territory and/or to defend any actions or proceedings involving the Product Trademarks in the Partner Territory, as the case may be.
- (c) If Partner does not initiate proceedings or take other appropriate action within ninety (90) calendar days after receipt of a request by Bioprojet to do so, then Bioprojet shall be entitled, at its own expense, to initiate infringement proceedings or take other appropriate action against an infringement of a Product Trademark in the Partner Territory, or to defend any actions or proceedings involving or affecting a Product Trademark in the Partner Territory, as the case may be.
- (d) The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the Product Trademarks in the Partner Territory nor the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.
- (e) In any event, the Parties shall keep one another informed of the status of their respective activities regarding any litigation in the Partner Territory involving a Product Trademark or settlement thereof and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party) and the other's expense.

(f) Partner and Bioprojet shall recover their respective actual out-of-pocket expenses, or proportionate percentages thereof, associated with any litigation against infringers undertaken pursuant to this Section 12.6 or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated between Partner and Bioprojet as set forth in the following table to the extent such recovery represents damages pertaining to the infringement of a Product Trademark in the Partner Territory:

Aggregate Recovery Amount in Excess of Out-of-Pocket Expenses	Payable to Bioprojet	Percentage Payable to Partner
Portion of such recovery less than or equal to US\$200,000,000	13%	87%
Portion of such recovery greater than US\$200,000,000 and less than or		
equal to US\$400,000,000	15%	85%
Portion of such recovery greater than US\$400,000,000 and less than		
US\$600,000,000	21%	79%
Portion of such recovery greater than US\$600,000,000	24%	76%

- 12.7 <u>Termination of Trade Mark License</u>. Partner's right to use the Product Trademarks and the Bioprojet trade name shall terminate in the Partner Territory upon termination or expiration of the Trademark License. Partner shall take all such steps as Bioprojet may reasonably request to give effect to the termination of the license to the Product Trademarks and Bioprojet trade name in the Partner Territory and to record any documents that may be required to evidence the termination of such license and transfer to Bioprojet of all rights, registrations, recordations and the like for such Product Trademarks.
- **12.8** <u>Domain Names</u>. The Parties shall discuss in good faith and agree upon how to handle domain names containing the Product Trademarks, as listed in Exhibit 12.8.

Article 13

TERM AND TERMINATION

13.1 Term. The term of this Agreement shall commence on the Signing Date and continue in force and effect, unless terminated earlier pursuant to Section 13.2, 13.3, 13.4 or 13.5 below, until expiration of the Royalty Term (such period, the "Term"). Upon the expiration of the Term, the licenses granted to Partner under Article 2 hereof will become non-exclusive, perpetual, irrevocable, fully paid up, non-assessable and non-royalty bearing (except for the Trademark Royalty Payment). If this Agreement is terminated pursuant to its terms prior to the Closing, Bioprojet shall promptly (and in any event within two (2) business days) execute and deliver, pursuant to the Escrow Agreement, a Termination Notice in the form attached as Exhibit E to the Escrow Agreement.

- 13.2 <u>Termination for Material Breach</u>. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or defaulted in the performance of any of its material obligations hereunder, and such default has continued for ninety (90) calendar days after written notice thereof was provided to the breaching Party by the non-breaching Party. Any such termination shall become effective at the end of such ninety (90) calendar day period unless the breaching Party has cured any such breach or default prior to the expiration of the ninety (90) calendar day period. Notwithstanding the provisions of this Section 13.2, Partner shall not have the right to terminate the Agreement for breach of any of Bioprojet's representations and warranties pursuant to Section 15.1 if prior to the Signing Date, Partner is aware of the fact or circumstances giving rise to such breach.
- 13.3 Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within ninety (90) calendar days after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within ninety (90) calendar days thereafter.
- **13.4** <u>Termination for Patent Challenge</u>. Bioprojet shall have the right to terminate this Agreement immediately upon notice to Partner if Partner, its Affiliate or its Sublicensees initiates or in any material respect, participates in or facilitates any action challenging the validity of Bioprojet Patents.

13.5 <u>Termination prior to the Closing Date</u>:

- (a) Bioprojet shall have the right to terminate this Agreement immediately upon notice to the other Party: (i) to the extent Bioprojet has made its HSR filing in material respect in accordance with this Agreement, if the Clearance Date does not occur, within two (2) months as from the Signing Date or (ii) if the Clearance Date has occurred but Partner has not provided to Bioprojet the Partner Closing Certificate.
- (b) Partner shall have the right to terminate this Agreement upon notice to Bioprojet (i) to the extent Partner has made its HSR filing in material respect in accordance with this Agreement, and diligently seeks Clearance, if the Clearance Date does not occur, within two (2) months as from the Signing Date or (ii) if the Clearance Date has occurred but Bioprojet has not provided to Partner the Bioprojet Closing Certificate.

Article 14

EFFECT OF TERMINATION

14.1 Accrued Obligations. The expiration or termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such expiration or

termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement.

14.2 Rights on Termination of Agreement in its Entirety. This Section 14.2 shall apply upon any termination of this Agreement in its entirety.

(a) Wind-down Period.

- (i) Commercialization. To avoid disruption in the availability of Product to patients, if this Agreement is terminated after the First Commercial Sale of the Product in the Partner Territory, Partner, its Affiliates and its Sublicensees shall continue to distribute the Product, in accordance with the terms and conditions of this Agreement, in the Partner Territory for which Regulatory Approval therefor has been obtained, until eighteen (18) months after the date on which Bioprojet notifies Partner in writing that Bioprojet has secured an alternative distributor or licensee for the Product in the Partner Territory, but in no event more for than thirty six (36) months after the effective date of any termination of this Agreement (the "Wind-down Period"); provided that Partner, its Affiliates and its Sublicensees shall cease such activities, or any portion thereof, in the Partner Territory upon sixty (60) calendar days' prior written notice by Bioprojet requesting that such activities (or portion thereof) be ceased. Notwithstanding any other provision of this Agreement, during the Wind-down Period, Partner's and its Affiliates' and, subject to Section 14.2(f) below, Sublicensees' rights with respect to the Product (including the Product Trademarks) in the Partner Territory shall be non-exclusive and, without limiting the foregoing, Bioprojet shall have the right to engage one or more other distributor(s) and/or licensee(s) of the Product in all or part of the Partner Territory and Partner shall not have any obligation to incur additional costs to distribute the Product. Any Product sold or disposed by Partner, its Affiliates and, subject to Section 14.2(f) below, its Sublicensees in the Partner Territory during the Wind-down Period, Partner shall notify Bioprojet of any quantity of the Product remaining in Partner's inventory and Bioprojet shall have the option, upon notice to Partner, to repurchase any such quantities of the Product from Partner at the transfer price paid by Partner for such Product.
- (b) <u>Assignment of Regulatory Filings and Regulatory Approvals</u>. Partner shall assign (or cause to be assigned) to Bioprojet or its designee (or to the extent not so assignable, Partner shall take all reasonable actions to make available to Bioprojet or its designee the benefits of) all Regulatory Filings for the Product in the Partner Territory, including any such Regulatory Filings made or owned by its Affiliates and/or Sublicensees. In each case, unless otherwise required by any applicable law or regulation or requested by Bioprojet, the foregoing assignment (or availability) shall be made within thirty (30) calendar days after the effective date of any termination of this Agreement. In addition, Partner shall promptly provide to Bioprojet a copy of all Data and Partner Know-How pertaining to the Product in the Partner Territory to the extent not previously provided to Bioprojet and Bioprojet shall have the right to use and disclose all Data and Partner Know-How pertaining to the Product following termination of this Agreement. In addition, all such Data and Partner Know-How, to the extent specifically pertaining to the Product, shall be deemed Confidential Information of Bioprojet and not Confidential Information of Partner (and will not be subject to the exclusions under Sections 10.1(a) or (e) above).

- (c) <u>Transition</u>. Partner shall use diligent efforts to cooperate at Bioprojet's expenses (or at Partner's expenses if this Agreement is terminated for Partner's breach) with Bioprojet, and/or its designee to effect a smooth and orderly transition in the development, sale and ongoing marketing, promotion and Commercialization of the Product in the Partner Territory during the Wind-down Period. Without limiting the foregoing, Partner shall, upon written request from Bioprojet, provide Bioprojet copies of customer lists, customer data and other customer information relating to the Product in the Partner Territory (except as prevented by the applicable laws and regulations relating to the protection of personal information), which Bioprojet shall have the right to use and disclose. Without limiting the foregoing, Partner shall use diligent efforts to conduct in an expeditious manner any activities to be conducted under this Section 14.2.
- (d) <u>Licenses</u>. Effective as of the date of expiration of the Wind-down Period, Partner hereby grants to Bioprojet an exclusive, worldwide, royalty-free license, with the right to grant sublicenses, under any Patents owned or Controlled by Partner related to the Product for the purposes of making, using, developing, importing, selling, distributing, marketing and promoting the Product.
- (e) Return of Materials. Within thirty (30) calendar days after the end of the Wind-down Period upon request by Bioprojet, Partner shall either return to Bioprojet or destroy all tangible items comprising, bearing or containing trade marks (including the Product Trademarks), trade names, patents, copyrights, designs, drawings, formulas or other Data, photographs, samples, literature, sales and promotional aids ("Product Materials") and Confidential Information of Bioprojet, that is in Partner's possession. Effective upon the end of the Wind-down Period, Partner shall cease to use all trademarks and trade names of Bioprojet (including the Product Trademarks) in the Partner Territory, and all rights granted to Partner hereunder with respect to the Product in the Partner Territory shall terminate.
- (f) <u>Sublicensees</u>. Any contracts with Sublicensees of the Product in the Partner Territory engaged by Partner shall, at the request of Bioprojet in its discretion, be assigned to Bioprojet to the furthest extent possible; provided that such assignment is accepted by the Sublicensee(s) in the Partner Territory. In the event such assignment is not requested by Bioprojet or is not accepted by such Sublicensee(s), then the rights of such Sublicensees with respect to the Product in the Partner Territory shall terminate upon the termination of Partner's rights with respect to the Partner Territory. Partner shall ensure that its Affiliates and such Sublicensees (if not assigned to Bioprojet pursuant to this Section 14.2(f)) shall transition all rights in and to the Product back to Bioprojet in the manner set forth in this Section 14.2 as if such Affiliate or Sublicensee were named herein.
- **14.3** No Renewal, Extension or Waiver. Acceptance of any order from, or sale or license of, any Product to Partner after the notice or effective date of expiration or termination of this Agreement in its entirety shall not be construed as a renewal or extension hereof, or as a waiver of expiration or termination of this Agreement in its entirety.

14.4 <u>Survival</u>. Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except those described in the following Sections: Sections 10.1, 10.2, 10.3, 10.4, 10.8, 11.3(b), 12.6(f), Article 13, Article 14, Article 16, Article 19, Sections 20.2, 20.4, 20.6, 20.11, and 20.12.

Article 15

REPRESENTATIONS, WARRANTIES AND COVENANTS

- 15.1 Representations and Warranties of Bioprojet. Bioprojet represents and warrants to Partner that, as of the Signing Date:
- (a) Bioprojet is a corporation duly organized, validly existing and is in good standing under the laws of France, is qualified to do business and is in good standing;
- (b) this Agreement and the other Transaction Documents are legal and valid obligations binding upon Bioprojet and enforceable in accordance with their respective terms. The execution, delivery and performance of this Agreement by Bioprojet has been duly authorized by all necessary corporate action and does not and will not in any material respect: (i) to Bioprojet's knowledge, violate any applicable law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Bioprojet; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding by which Bioprojet is bound;
 - (c) Bioprojet has the full right and authority to grant the rights and licenses as provided herein;
- (d) Bioprojet has not previously granted any right, license or interest in or to the Bioprojet Patents, or any portion thereof, that is in conflict with the rights or licenses granted to Partner under this Agreement;
- (e) there is no action or proceeding pending against Bioprojet that questions in any material respect the validity of this Agreement or any action taken by Bioprojet in connection with the execution of this Agreement;
- (f) except for the NDA approval by the FDA and the HSR Clearance, Bioprojet has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement;
- (g) to Bioprojet's actual knowledge, the Bioprojet Patents, Product Trademarks, and Bioprojet Know-How do not infringe the intellectual property of any Third Party;
- (h) to Bioprojet's actual knowledge, there is no infringement by a Third Party of any of the Bioprojet Patents or the Bioprojet Know-How;

- (i) other than the opposition against the corresponding EP 1863487 patent in Europe, to Bioprojet's actual knowledge, none of the issued Bioprojet Patents are invalid or unenforceable; and
- (j) Bioprojet is in compliance in all material respects with all, and has not violated in any material respect any, applicable laws with respect to the conduct of its business or the ownership or operation of its properties or assets. Bioprojet is in compliance with, and has conducted and does not have any director, officer, agent, employee, affiliate or other representative who is debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation; excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7 et seq. or any state agency from participation in any federal or state health care program; or otherwise disqualified or restricted by FDA pursuant to 21 C.F.R. § 312.70 or any other regulatory authority.
 - 15.2 Covenants, Representations and Warranties of Partner. Partner represents and warrants to Bioprojet that, as of the Signing Date:
- (a) Partner is a limited liability company duly organized, validly existing and is in good standing under the laws of the State of Delaware and is qualified to do business and is in good standing in each other state in which the failure to be so qualified and in good standing would result in a material adverse effect;
- (b) Partner's and its shareholders' issued capital and voting rights are held as set forth in Schedule 15.2(b); Paragon Health Equitty LLC's issued capital and voting rights are held as set forth in Schedule 15.2(b);
 - (c) Partner has hired Bob Repella as its CEO;
- (d) this Agreement and the other Transaction Documents are legal and valid obligations binding upon Partner and enforceable in accordance with their respective terms. The execution, delivery and performance of this Agreement by Partner has been duly authorized by all necessary limited liability company action and does not and will not in any material respect: (i) require the consent or approval of Partner's stockholders; (ii) to Partner's knowledge, violate any applicable law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Bioprojet; nor (iii) conflict with, or constitute a default under, any agreement, instrument or understanding, by which Partner is bound;
 - (e) Partner has the full right and authority to grant the rights and licenses granted herein;
- (f) there is no action or proceeding pending against Partner that questions in any material respect the validity of this Agreement or any action taken by Partner in connection with the execution of this Agreement;
 - (g) Partner has conducted an independent due diligence on the Licensed Assets and the Product, with the assistance of its advisers; and

- (h) Partner is in compliance in all material respects with all, and has not violated in any material respect any, applicable laws with respect to the conduct of its business or the ownership or operation of its properties or assets, including the following laws, as applicable: (i) the laws composing the Medicare and Medicaid Programs, including applicable provisions of the Social Security Act (e.g., Civil Monetary Penalties Act, 42 U.S.C. § 1320a-7a, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b), (ii) (x) any other laws prohibiting rebates, kickbacks, fee-splitting or other financial incentives or inducements, including providing products or services below cost for the referral or continuation of business, and (y) the False Claims Act, 31 U.S.C. § 3729 et seq., and (iii) laws enforced by the FDA, including the FDCA and Section 21 of the C.F.R. Partner is in compliance with, and has conducted and does not have any director, officer, agent, employee, affiliate or other representative who is debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation; excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7 et seq. or any state agency from participation in any federal or state health care program; or otherwise disqualified or restricted by FDA pursuant to 21 C.F.R. § 312.70 or any other regulatory authority.
- 15.3 <u>DISCLAIMER</u>. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.
- 15.4 HSR Filing. Promptly following the Signing Date and no later than two (2) business days thereafter, each Party will promptly prepare and submit any necessary filings with the Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") under the US's Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a) ("HSR") with respect to this Agreement and the transactions contemplated hereby (collectively, the "HSR Filing") and will use commercially reasonable efforts to obtain expiration of waiting period. Each Party will be responsible for its own costs; provided that Partner will pay all filing fee(s) required in the event of an HSR filing or filing for other governmental clearance. Both Parties will use all commercially reasonable efforts to cause the clearance to be obtained as quickly as possible. However, neither Party will be required to adversely affect its legal position (e.g., agree to divestitures or product restrictions) in the interest of expediting such clearance. In the event that any such approval or expiration of waiting period, as applicable, does not occur within two (2) months as from the Signing Date, either Party may terminate this Agreement under the conditions set forth in Section 13.5 herein.

INDEMNIFICATION

16.1 <u>Indemnification of Bioprojet</u>. Partner shall indemnify and hold harmless each of Bioprojet, its Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the "<u>Bioprojet Indemnitees</u>"), from and against any and all liabilities, damages, penalties, fines, costs, expenses, claims, actions, suits or proceedings (including, reasonable attorneys' fees and other expenses of litigation) ("<u>Liabilities</u>")

incurred by any Bioprojet Indemnitee as a result of: (a) claims, actions, suits or proceedings brought by a Third Party (a "Third Party Claim") arising from or in connection with the use or Commercialization of any Product by or on behalf Partner, its Affiliates or Sublicensees in the Partner Territory including, any Product Liability Claim in the Partner Territory; (b) any breach of any representations, warranties or covenants by Partner in Article 15 above; (c) any of the representations and warranties given by Partner in Section 15.2 hereof being untrue or incorrect as of the Effective Date (as if given on the Effective Date) in any material respect as a result of Partner's actions or inactions during the period beginning on the Signing Date and ending on the Effective Date (including without limitation the items disclosed by Partner pursuant to clause (A) of Section 17.2(a)(i)), except to the extent such Liabilities fall within the scope of Bioprojet's indemnification obligations set forth in Section 16.2 below or result from the willful misconduct of a Bioprojet Indemnitee.

- 16.2 Indemnification of Partner. Bioprojet shall indemnify and hold harmless each of Partner, its Affiliates and Sublicensees and the directors, officers and employees of Partner, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "Partner Indemnitees"), from and against any and all Liabilities incurred by any Partner Indemnitee as a result of: (a) a Third Party Claim arising from or in connection with the use or Commercialization of any Product by or on behalf Bioprojet or its licensee in the Bioprojet Territory; (b) any breach of any representations, warranties or covenants by Bioprojet in Article 15 above; (c) any of the representations and warranties given by Bioprojet in Section 15.1 hereof being untrue or incorrect as of the Effective Date (as of given on the Effective Date) in any material respect as a result of Bioprojet's actions or inactions during the period beginning on the Signing Date and ending on the Effective Date (including without limitation the items disclosed by Bioprojet pursuant to clause (A) of Section 17.2(b)(i)); or (d) if the Clearance Date has occurred, any suit, action or other proceeding pending or threatened before any court, governmental body or administrative or other agency (whether filed or arising before, on or after the Clearance Date) wherein an unfavorable injunction, judgment, order, decree, ruling or charge could be reasonably likely to (A) prevent the performance of this Agreement or the consummation of any of the transactions contemplated hereby or declare unlawful any of the transactions contemplated hereby, or (B) cause any of the transactions contemplated by this Agreement to be rescinded following consummation; except to the extent such Liabilities fall within the scope of Partner's indemnification obligations set forth in Section 16.1 above or result from the willful misconduct of a Partner Indemnitee.
- 16.3 Procedure. A Party that intends to claim indemnification under this Article 16 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Section 16.3 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 16.3, but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Section 16.3. The Indemnitee under this Section 16.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

- 16.4 <u>Disclaimer of Liability.</u> IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE OR OTHERWISE. NOTWITHSTANDING THE FOREGOING, THIS DISCLAIMER DOES NOT APPLY TO LIABILITY OR DAMAGES (A) RESULTING FROM A BREACH OF CONFIDENTIALITY OBLIGATIONS OF A PARTY UNDER <u>ARTICLE 10</u>, OR (B) SUBJECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO <u>SECTIONS 16.1</u> AND <u>16.2</u>. For the avoidance of doubt, out-of-pocket costs shall not by their sole nature be deemed indirect or incidental damages and may be regarded as direct damages to the extent directly related to the breach.
- 16.5 <u>Insurance</u>. Each Party shall secure and maintain in effect, during the Term of this Agreement and for a period of **five (5)** years thereafter, comprehensive general liability insurance (including product liability insurance), underwritten by a reputable insurance carrier, in a form and having liability limits standard and customary for entities in the pharmaceutical industry based on such Party's activities and indemnification obligations under this Agreement, as applicable. Each Party shall furnish to the other Party, on request, certificates of insurance setting forth the amount of liability insurance and shall provide the other Party at least thirty (30) calendar days' written notice prior to any termination or material reduction to the level of coverage.

CLOSING

17.1 Closing. Subject to the satisfaction of the conditions set forth in Section 17.2 below, the closing (the "Closing") of the transactions contemplated by this Agreement shall take place in no event later than the third business day following the date on which all the conditions set forth in Section 17.2 below shall have been satisfied or waived, unless another time and/or date is agreed to by Partner and Bioprojet in writing.

17.2 Closing Conditions.

- (a) The obligation of Bioprojet to consummate the Closing is subject to the satisfaction of the following conditions on or prior to the Closing:
- (i) Partner shall deliver to Bioprojet a certificate signed by Partner, dated the Effective Date, stating that (A) except as otherwise disclosed on such certificate, during the period beginning on the Signing Date and ending on the Effective Date Partner has taken no action, or failed to take any action, that resulted in the representations and warranties given by Partner in Section 15.2 hereof being untrue or incorrect as of the Effective Date and (B) except as otherwise disclosed on such certificate, as of the Effective Date, Partner does not have actual knowledge that any of the representations and warranties given by Partner in Section 15.2 are untrue or incorrect as of the Effective Date; and

- (ii) the Clearance Date shall have occurred.
- (b) The obligation of Partner to consummate the Closing is subject to the satisfaction of the following conditions on or prior to the Closing:
- (i) Bioprojet shall deliver to Partner a certificate signed by Bioprojet, dated the Effective Date, stating that (A) except as otherwise disclosed on such certificate, during the period beginning on the Signing Date and ending on the Effective Date Bioprojet has taken no action, or failed to take any action, that resulted in the representations and warranties given by Bioprojet in Section 15.1hereof being untrue or incorrect as of the Effective Date and (B) except as otherwise disclosed on such certificate, as of the Effective Date, Bioprojet does not have actual knowledge that any of the representations and warranties given by Bioprojet in Section 15.1 are untrue or incorrect as of the Effective Date; and
 - (ii) the Clearance Date shall have occurred.

EXCLUSIVITY

18.1 Exclusivity. During the period beginning on the Signing Date and ending upon the Effective Date or termination of this Agreement in accordance with its terms, Bioprojet shall not engage in discussions or negotiations (or provide information to) any Third Party (regardless of whether such Third Party has been contacted by Bioprojet or its representatives before and whether such Third Party has previously engaged in discussions or negotiations with Bioprojet or its representatives), solicit offers or enter into any binding agreement or non-binding term sheet with any Third Party whatsoever regarding the Commercialization of the Product in the Partner Territory that conflicts with this Agreement.

Article 19

DISPUTE RESOLUTION

19.1 Arbitration.

(a) In the event a dispute arises (each, a "*Dispute*"), either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "*Arbitration Request*") under the Rules of Arbitration of the International Chamber of Commerce (the "*Rules*") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "*Arbitration*"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language. The place of arbitration shall be Paris, France. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators.

- (b) <u>Confidentiality</u>. Except to the limited extent necessary to comply with applicable law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.
- (c) <u>Communications with Internal Counsel</u>. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of applicable law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

GENERAL PROVISIONS

- **20.1** Force Majeure. If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of such Party (including, fire, flood, earthquake, tsunami, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, acts of God or any acts, omissions or delays in acting of the other Party), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.
- **20.2** <u>Governing Law.</u> This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement and resolution of all Disputes and any remedies relating thereto, shall be governed by, and construed and enforced in accordance with, the laws of England and Wales, without reference to conflict of law principles.
- **20.3** <u>Waiver of Breach</u>. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

- **20.4** <u>Modification</u>. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.
- 20.5 Severability. In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Agreement upon sixty (60) days' prior written notice to the asserting Party, unless such assertion is eliminated and the effect of such assertion cured within such sixty (60) day period. Any termination in accordance with the foregoing shall be deemed a termination under Section 13.2 by reason of a breach by the Party who made such assertion.
- **20.6** Entire Agreement; Amendments. This Agreement (including the Exhibits attached hereto), together with the Transaction Documents (when executed), constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.
- 20.7 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be in writing in the English language, and (a) delivered personally, (b) sent by express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission or facsimile (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

<u>To Bioprojet</u>: <u>To Partner</u>:

Bioprojet Société Civile de Recherche [Address]

Harmony Biosciences, LLC [Address]

With a copy to: With a copy to:

McDermott Will & Emery [Address]

Katten Muchin Rosenman LLP

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

20.8 <u>Assignment</u>. This Agreement shall not be assignable by either Party to any Third Party hereto without the written consent of the other Party hereto. Either Party shall have the right to assign this Agreement to an Affiliate, with the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed); provided that the assigning Party guarantees the performance of this Agreement by such Affiliate and such Affiliate agrees in a writing delivered to the non-assigning Party to assume all of the rights and obligations of the assigning Party under this Agreement; and further provided that if the non-assigning Party reasonably believes such assignment could result in material adverse tax consequences to the non-assigning Party, the non-assigning Party shall have no obligation to consent to the proposed assignment. Subject to the foregoing and to Section 20.9 below, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 20.8 shall be null and void.

20.9 <u>Change of Control.</u> During the portion of the Term ending on the third (3rd) year anniversary of the first NDA approval by the FDA (the "<u>Initial Partner Restricted Period</u>"), Partner agrees not to solicit or initiate a sale process with respect to a controlling interest of its equity or all, or substantially all, of its assets (each a "<u>CoC Transaction</u>"), without the prior written consent of Bioprojet, in Bioprojet's sole discretion; provided that no such consent shall be required if Partner (or a successor corporate entity created for purposes of an initial public offering) undergoes an initial public offering of its equity (an "<u>IPO</u>"), in which case, Partner's and its Affiliates' senior executive management team will be subject to any normal and customary lock-up conditions (if any) to be agreed upon with the lead underwriter of the IPO.

If Partner and its board of directors hire an investment banker with respect to or otherwise decide to explore, a CoC Transaction during the Initial Partner Restricted Period or the subsequent two (2) year period, Partner shall provide Bioprojet with prompt written notice thereof, together with the information reasonably requested by Bioprojet to assess such CoC Transaction, and grant Bioprojet a sixty (60) calendar day right of first offer with respect to the equity or assets contemplated to be sold in such CoC Transaction (the "Right of First Offer"). During such sixty (60) calendar day period (as may be extended by written agreement of the Parties), Partner shall exclusively negotiate with Bioprojet in good faith such CoC Transaction; provided; however, that such obligation to negotiate shall in no event be deemed to require Partner to consummate a CoC Transaction with Bioprojet on terms that Partner does not find reasonable in its sole discretion.

After expiration of such sixty (60) calendar day Right of First Offer period, Bioprojet will be entitled to participate in any subsequent bidding process along with the other Third Party bidders and will be provided the same information as those Third Party bidders. If any such CoC Transaction is consummated with a Third Party(ies), Partner shall remain obligated with respect to all of its ongoing contractual obligations under this Agreement subsequent to the closing of such CoC Transaction.

In addition, except (a) in the case of an IPO or (b) with the prior written consent of Bioprojet, in Bioprojet's sole discretion, during the portion of the Term ending on the fifth (5th) year anniversary of the first NDA approval by the FDA, Jeff Aronin shall not transfer or assign ownership of more than forty-nine percent (49%) of his equity interest (directly or indirectly) in Partner at Closing; provided, however, that, with respect to a CoC Transaction involving the sale of the equity of Partner, if (i) a buyer requires 100% equity ownership in Partner (including the entire equity interests held by Jeff Aronin) be included in such CoC Transaction and (ii) Partner's board of directors determines that it has a fiduciary responsibility to cause the sale of 100% of the equity in Partner in such CoC Transaction, then Jeff Aronin shall be permitted to sell his entire equity interests (direct or indirect) in Partner, provided that, in such case and only such case, Bioprojet shall then be entitled to a one-time, non-creditable, non-refundable payment of Fifteen Million (\$15,000,000) USD by Partner upon the closing of such CoC Transaction. From and after the fifth (5th) year anniversary of the NDA approval by the FDA, Jeff Aronin shall have the right to sell his equity interest (either direct or indirect and in whole or in part) in Partner without Bioprojet's consent or the other restrictions set forth above.

- **20.10** No Partnership or Joint Venture. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Partner and Bioprojet. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.
- **20.11** Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement. All references to "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States or France.
- **20.12** <u>Counterparts; Other Matters.</u> This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

IN WITNESS WHEREOF, the Parties have executed this License and Commercialization Agreement as of the date first set forth above.

Bioprojet Société Civile de Recherche

BY: /s/ Jeanne-Marie Lecomte

NAME: Jeanne-Marie Lecomte

TITLE: CEO

Harmony Biosciences, LLC

BY: /s/ Jeff Aronin

NAME: Jeff Aronin TITLE: Chairman

IN WITNESS WHEREOF, the Parties have executed this License and Commercialization Agreement as of the date first set forth above.

Bioprojet Société Civile de Recherche

BY: /s/ Jeanne-Marie Lecomte

NAME: Jeanne-Marie Lecomte

TITLE: CEO

Harmony Biosciences, LLC

BY: /s/ Jeff Aronin

NAME: Jeff Aronin TITLE: Chairman

EXHIBIT 1.4

Existing Bioprojet manufacturing agreements

Current CMO	QT Agreement (with date of signature)	Supply Agreement (with date of signature)	
Patheon FP 4.5 mg	CDC-QUA-233-02 (signed 14th June, 2016)	C-BRP-90182-R3 (signed 3rd June, 2016)	
Patheon FP 18 mg	CDC-QUA-233-02 (signed 14th June, 2016)	Amendment to 4.5 mg agreement currently under signature at Path	
Corden (ex Synkem) API	CDC-QUA-237-01 (signed 21st April, 2015	Currently under signature at Corden	

EXHIBIT 1.7

Bioprojet Patents

PRIORITY	Filing	DESIGNATION	COUNTRY	STATUS (MM/DD/YY)
EP 98 401 944.8 and	1998	Compound	Europe	Issued. Exp. Date : 07/29/2019
EP 98 403 351.4	2004	BF 2.649	1st division	Issued. Exp. Date : 07/29/2019
(Réf. A21&A23)	2006		2nd division	Inactive since 2015
extended deadline:	1999		U.S.A.	Issued. Exp. Date : 07/29/2019
	2004		1st division	Issued. Exp. Date: 02/02/2020
suppl protection certificate	2006		2 nd division	Issued. Exp. Date : 07/29/2019
accepted (all EP countries	2010		3rd division	Inactive since 2015
listed)	1999		Canada	Issued. Exp. Date : 07/29/2019
	1999		Japan	Issued. Exp. Date : 07/29/2019
			1st division	Issued. Exp. Date: 07/29/2019
Fr 03-07 836	2003	BF 2.649	Europe	Issued. Exp. Date: 04/05/2026
(Réf. A31)		+	U.S.A.	Issued. Exp. Date : 10/21/2027
· · ·		olanzapine	Canada	Issued. Exp. Date : 06/25/2024
		•	Japan	Issued. Exp. Date : 06/25/2024
			Mexico	Issued. Exp. Date : 06/25/2024
			South Korea	Inactive since 2012
EP 05290728.4	2005	BF 2.649	Europe	Inactive since 2008
(Réf. A37)		in	U.S.Â.	
		Epilepsy	Canada	
			Japan	
			Mexico	
			South Korea	

PRIORITY	Filing	DESIGNATION	COUNTRY	STATUS (MM/DD/YY)
EP 05 290 727.6 and US	2005	BF 2.649	Europe	Examination in progress
60/668,618		in	Norway	Examination in progress
(Réf. A38 & A43)		Parkinson's disease	Eurasia, Ukraine	Issued. Exp. Date: 03/30/2026
			U.S.A.	Issued. Exp. Date: 03/30/2029
			Canada	Issued. Exp. Date: 03/30/2026
			Brazil	Examination in progress
			Colombia	Inactive since 2013
			Ecuador	Inactive since 2015
			Mexico	Issued. Exp. Date: 03/30/2026
			China, India, Japan	Issued. Exp. Date: 03/30/2026
			Philippines, Sth Korea	Issued. Exp. Date: 03/30/2026
			Singapore	Issued. Exp. Date: 03/30/2026
			Vietnam	Examination in progress
			Algeria, Tunisia,	Examinations in progress
			Egypt, Libya	Examinations in progress
			Morocco, AOPI	Issued. Exp. Date: 03/30/2026
			South Africa	Issued. Exp. Date: 03/30/2026
			Australia	Issued. Exp. Date: 03/30/2026
			New Zealand	Issued. Exp. Date: 03/30/2026
Fr 06-06 697	2006	BF 2.649	Europe	Inactive since 2012
(Réf. A49)		+	Eurasia	
		modafinil	U.S.A., Canada Brazil, Mexico	
			China, India, Japan	

PRIORITY	Filing	DESIGNATION	COUNTRY	STATUS (MM/DD/YY)
EP 05 100 942.1	2005	BF 2.649	Europe	Issued. Exp. Date : 02/06/2026
(Réf. A50)		Salt	U.S.A.	Issued. Exp. Date : 02/25/2029
			Division	Issued. Exp. Date: 02/06/2026
			Canada	Issued. Exp. Date: 02/06/2026
			Argentina	Inactive since 2016
			Uruguay	Examination in progress
			Chile, Mexico	Issued. Exp. Date : 02/09/2026
			China	Issued. Exp. Date: 02/06/2026
			Sth Korea, India,	Issued. Exp. Date: 02/06/2026
			Japan	Issued. Exp. Date: 02/08/2026
			Taiwan	
EP 05 106 263.6	2005	BF 2.649	Europe	Inactive since 2008
(Réf. A51)		Process	Argentina	Inactive since 2014
			Uruguay	Examination in progress
			Chile	Inactive since 2009
			India	Issued. Exp. Date: 07/05/2026
			Taiwan	Issued. Exp. Date : 07/04/2026

EXHIBIT 1.40

Product Trademarks

26 juin 2017

COUNTRIES / TRADEMARKS

Country United States of America

<u>Trademark</u> WAKREM	Registered Owner BIOPROJET EUROPE LTD	<u>Classes</u> 5	No / Date Application 87377316 20 mars 2017	No / Date Registration	<u>Status</u> Pending	Next Renewal Due
WAKIX	BIOPROJET EUROPE LTD	5	1211316 25 juin 2014	4680400 03 Novr. 2015	Registered	25-juin-2024

EXHIBIT 5.1

Initial Commercialization Plan

[***]

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EXHIBIT 9.1

Key terms of the Supply Agreement

- 1. <u>Current Suppliers</u>. Bioprojet has entered into the agreements with current API and Product suppliers on terms that have been provided to Partner (the "Existing Agreement"). The Supply Agreement shall be consistent with such agreements and Bioprojet shall not be obliged to take over obligations that its current suppliers do not have in the Existing Agreements.
- 2. <u>Forecasts</u>. Partner shall provide Bioprojet with its rolling forecasts ten (10) days in advance of any launch forecast being owed to one of the current Bioprojet's existing suppliers; such rolling forecasts shall become binding upon Partner at the time and to the extent that Bioprojet's corresponding forecast is binding upon Bioprojet.
- 3. <u>Acceptance of orders and lead time</u> shall be consistent with the Existing Agreement and Bioprojet's supply chain.
- 4. <u>Safety Stock</u>. Bioprojet shall hold six (6) months of API and/or Product as commercial safety stock available solely to Partner, at Partner's costs.
- 5. <u>Non-Conforming Product</u>. If Bioprojet delivers Product that does not conform to the applicable warranties set forth in the Supply Agreement, then Bioprojet shall, at Partner's election, promptly refund the transfer price paid for such non-conforming product or reperform the manufacturing of Product and supply conforming Product at no additional cost to Partner.
- 6. <u>Failure to Deliver</u>. In the event of a failure to deliver, Partner will have the right to manufacture and/or hire its own CMO.
- 7. <u>Limitation of Remedies</u>. Bioprojet's liability in relation to a failure to supply by the applicable delivery date or a failure of such supplied additional quantities of API or Product to comply with the specifications therefor shall be capped to 100% of the aggregate price received by Bioprojet for the supply of API and Product over the 12-month period prior to such failure. In no event shall Bioprojet be liable to Partner or any of its Affiliates or Sublicensees for special, incidental, indirect, consequential or other monetary damages (including lost profits) in relation to a failure to satisfy its supply obligations.
- 8. Other Terms. Other customary terms and provisions applicable to supply agreements for pharmaceutical products.

EXHIBIT 12.8

Domain Names

- wakix.us
- wakirem.us

(currently under registration process)

<u>Schedule 15.2(b)</u>

Ownership and Voting

Harmony Biosciences, LLC

Member	Harmony Biosciences, EEC	Ownership
Harmony Biosciences II, LLC		100%
	Harmony Biosciences II, LLC	
Member		Ownership
Marshman Fund Trust II U/A/D 5/1/0	08	100%
	Paragon Health Equity, LLC	
Member		Ownership
Marshman Fund Trust I		99%
Lisa Aronin		<u> </u>
TOTALS:		100%

AMENDMENT NO. 1

TO

LICENSE AND COMMERCIALIZATION AGREEMENT

This Amendment No. 1, dated as of August 27, 2018 (this "Amendment"), to the License and Commercialization Agreement (the "Agreement"), dated as of July 28, 2017, is entered into between Bioprojet Societe Civile de Recherche, an independent (privately) owned research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France ("Bioprojet SCR") and together with its Affiliates, including Bioprojet Pharma SARL and Bioprojet Europe Ltd., "Bioprojet"), and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania 19462 USA ("Partner"). Capitalized terms used, but not otherwise defined, in this Amendment shall have the meanings ascribed to them in the Agreement. Bioprojet and Partner may be referred to herein, together, as the "Parties" and, individually, as a "Party."

WHEREAS, the Parties have previously entered into the Agreement; and

WHEREAS, in accordance with the Agreement, the Parties desire to amend the Agreement, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the adequacy and receipt of which hereby are acknowledged, the Parties hereby agree as follows:

- 1. Subject to timely payment of the milestone amount pursuant to Section 6.2(iv), Section 6.2(iv) of the Agreement is hereby amended by deleting the clause ", and pay any corresponding milestone payment within fifteen (15) days of such achievement." and replacing it with the following clause:
 - ", and pay any corresponding milestone payment (a) payable under Section 6.2(i) or Section 6.2(iii) within fifteen (15) days of such achievement and (b) payable under Section 6.2(ii), together with a one-time, non-creditable, non-refundable payment in the amount of Two Million (\$2,000,000) USD, within ninety (90) days of such achievement."
- 2. This Amendment shall be governed, and construed and enforced in accordance with, the laws of England and Wales, without reference to conflict of law principles.
- 3. This Amendment may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures hereto were upon the same instrument. This Amendment shall become effective when each Party shall have received a counterpart hereof signed by the other Party. Until and unless each Party has received a counterpart hereof signed by the other Party hereto, this Amendment shall have no effect, and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication).

- 4. Except as otherwise provided herein, the Agreement shall remain unchanged and in full force and effect.
- 5. From and after the execution of this Amendment by the Parties, any reference to the Agreement shall be deemed to be a reference to the Agreement as amended by this Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the day and year first written above.

BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE

y: /s/ Jeanne-Marie Lecomte

Name: Jeanne-Marie Lecomte

Title: Chairman

HARMONY BIOSCIENCES, LLC

By: /s/ John Jacobs

Name: John Jacobs

Title: EVP & Chief Commercial Officer

[Signature Page to Amendment No. 1 to License and Commercialization Agreement]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

TRADEMARK LICENSE AGREEMENT

This Trademark License Agreement (this "Agreement") is entered into this 23rd day of August, 2018 (the "Effective Date") by and among Bioprojet Europe, Ltd., a company organized under the laws of Ireland and having its place of business at 101 Furry Park Road, Killester, Dublin 5, D05KD52 Ireland ("Licensor"), Bioprojet Société Civile de Recherche, an independent (privately owned) research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France ("Bioprojet"), and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 1033 Skokie Boulevard, Suite 600, Northbrook, Illinois 60062 ("Licensee"). Licensor, Bioprojet, and Licensee hereafter are collectively referred to as the "Parties," and each individually is referred to as a "Party," where no other distinction is required.

BACKGROUND

WHEREAS, in connection with its business, Licensor is the owner of U.S. Trademark Registration No. 4,680,400 for the mark WAKIX designating "pharmaceutical products for the treatment of narcolepsy or other sleep disorders" in International Class 5, U.S. Trademark Application No. 87377316 for the mark WAKIREM designating "pharmaceutical preparations for the treatment of narcolepsy or other sleep disorders" in International Class 5 and the trade name "Bioprojet".

WHEREAS, Licensor is an affiliate of Bioprojet, owner of certain registered trademarks and trademark applications in the United States of America designating products developed by Bioprojet.

WHEREAS, Licensee and Bioprojet are parties to a License and Commercialization Agreement dated July 28, 2017 (the "<u>L&C Agreement</u>"), pursuant to which, among other things, Bioprojet granted to Licensee, and Licensee obtained certain exclusive rights and licenses under the Licensed Assets to Commercialize the Product in the Field and the Territory, all as defined and more specifically set forth therein. All capitalized terms not otherwise defined herein shall have the meaning assigned to them in the L&C Agreement.

WHEREAS, pursuant to the terms of the L&C Agreement, Bioprojet granted to Licensee the exclusive right and license to use the trademarks identified on Exhibit A, attached hereto and made a part hereof, Bioprojet's trade name and any other product-specific trademarks that Bioprojet and Licensee mutually agree upon for use with the Product in the Territory during the Term (each, individually, the "Trademark", and, collectively, the "Trademarks") in the United States and its territories, commonwealths and protectorates (including Puerto Rico) (the "Territory") for the marketing, sale and promotion of the Product.

WHEREAS, the Parties have agreed upon the brand guidelines for the Product as set forth on Exhibit B, attached hereto and made a part hereof.

WHEREAS, the Parties are desirous of entering into this Agreement to more fully set forth the terms on which the rights to use the Trademarks and the Bioprojet trade name, as provided in the L&C Agreement, are granted to Licensee.

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein and in the L&C Agreement and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is agreed as follows:

1. Grant of License; Consideration.

- (a) Licensor hereby grants to Licensee an exclusive license to use (and grant sublicenses to Licensee's Affiliates and Third Parties to use in accordance with the provisions of the L&C Agreement) the Trademarks and the Bioprojet trade name in the Territory for the sole purpose of marketing, selling, distributing and promoting the Product in accordance with this Agreement and, as applicable, the L&C Agreement. Licensor further agrees to be bound by the terms and conditions of the L&C Agreement to the extent necessary for Licensee to fully receive the rights granted by Bioprojet thereunder with respect to the Trademarks and other matters addressed in this Agreement.
- (b) In consideration for the Trademark License, following the First Commercial Sale of Product and for twenty (20) years thereafter (the "Initial Term"), Partner shall pay to Bioprojet the Trademark Royalty Payments (as defined in the L&C Agreement) pursuant to Section 6.3(b) of the L&C Agreement.

2. Term.

- (a) This Agreement shall commence on the Effective Date and shall continue for the Initial Term, unless sooner terminated as provided herein.
- (b) This Agreement may be extended, at Licensee's option on a non-exclusive basis, for two (2) further renewal periods of five (5) years each, commencing upon the expiration of the Initial Term (each, a "Renewal Term"), provided that: (i) Licensee is not in breach of any material obligation under this Agreement as of the date of Licensee's exercise of such renewal or extension hereof and as of the commencement of each Renewal Term; and (ii) Licensee gives written notice to Licensor by no later than six (6) months prior to the expiration of the then current term of its exercise of Licensee's option for the following Renewal Term. All terms and conditions of this Agreement shall remain in full force and effect for the Renewal Term(s), unless the Parties mutually agree otherwise in writing signed by or on behalf of all Parties. The Initial Term and the Renewal Term(s), if any, shall constitute the "Term." The Term shall also be deemed to refer to only the Initial Term if Licensee's first renewal option is not exercised.

3. Display.

(a) Except as set forth in this Section 3, all packaging materials, labels and Marketing Materials for the Product shall display one of the Trademarks, and no other

product-specific trademarks or branding. Where possible, Licensee shall utilize the mark "WAKIX" as the source identifier for the Product, or any other registered trademark designated as such by Licensor. If "WAKIX" cannot be used for legal, regulatory or other material reasons outside the Parties' reasonable control, in the Territory, Licensee shall utilize the alternative registered trademark, chosen by Licensor as the Trademark. If neither "WAKIX" or the alternative trademark can be used for legal, regulatory or other material reasons outside the Parties' reasonable control, in the Territory, the Parties will agree as to another Trademark to be filed and maintained by Licensor for use in the Territory and such other trademark shall be deemed to be included in the definition of "Trademarks" herein.

- (b) The Product shall be sold in the Territory under the trade name of Licensee; provided, however that to the extent permissible under applicable law within the Territory, such packaging materials, labels and Marketing Materials shall also display the trade name of Licensor in reasonable size and prominence, as reasonably approved by Licensor. The trademarks of Licensee, trade dress, style of packaging and the like with respect to the Product in the Territory may be determined by Licensee in a manner that is consistent with Licensee's standard trade dress and style, but shall be subject to the approval by the JSC (as defined in the L&C Agreement).
- 4. <u>Approval of Packaging and Promotional Materials</u>. Licensee shall submit representative Marketing Materials, packaging and Product displaying the Trademarks and/or Licensor's trade name to Licensor for Licensor's review and approval prior to the first use of such Marketing Materials, packaging or Product and prior to any subsequent change or addition to such Marketing Materials, packaging or Product; provided that if Licensor has not responded within thirty (30) calendar days after the submission of such Marketing Materials, packaging or Product, Licensor's approval will be deemed to have been received.

5. Enforcement.

- (a) If either Party becomes aware of any actual or threatened infringement of any Trademark in the Territory, such Party shall promptly notify the other Party in writing.
- (b) Licensee shall have the first right, at its own expense, to initiate infringement proceedings or take other appropriate actions against an infringement of any Trademark in the Territory and/or to defend any actions or proceedings involving the Trademarks in the Territory, as the case may be.
- (c) If Licensee does not initiate proceedings or take other appropriate action within ninety (90) calendar days after receipt of a request by Licensor to do so, then Licensor shall be entitled, at its own expense, to initiate infringement proceedings or take other appropriate action against an infringement of a Trademark in the Territory, or to defend any actions or proceedings involving or affecting a Trademark in the Territory, as the case may be.
- (d) The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the Trademarks in the Territory nor the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

- (e) In any event, the Parties shall keep one another informed of the status of their respective activities regarding any litigation in the Territory involving a Trademark or settlement thereof and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party) and the other's expense.
- (f) Licensee and Licensor shall recover their respective actual out-of-pocket expenses, or proportionate percentages thereof, associated with any litigation against infringers undertaken pursuant to this Section 5 or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated between Licensee and Licensor as set forth in the following table to the extent such recovery represents damages pertaining to the infringement of a Trademark in the Territory:

Aggregate Recovery Amount in Excess of Out-of-Pocket Expenses	Percentage Payable to Licensor	Percentage Payable to Licensee
Portion of such recovery less than or equal to US\$200,000,000	13%	87%
Portion of such recovery greater than US\$200,000,000 and less than or		
equal to US\$400,000,000	15%	85%
Portion of such recovery greater than US\$400,000,000 and less than		
US\$600,000,000	21%	79%
Portion of such recovery greater than US\$600,000,000	24%	76%

6. Representations and undertakings.

6.1. <u>Representations of Licensor</u>. Licensor represents and warrants that: (a) it owns outright all marketable and other title to the Trademarks, free and clear of all liens, security interests, encumbrances, and/or any other transfer of rights; (b) it is not currently a party to any agreement which grants any other party the right to use the Trademarks in the Territory; (c) to Licensor's knowledge, the use of the Trademarks does not infringe upon any trademark owned by any Third Party (as defined in the L&C Agreement) in the Territory; and (d) Licensor has full power and authority to enter into this Agreement, to perform its obligations hereunder and to grant the rights it grants herein.

6.2. Representations and undertakings of Licensee.

(a) Licensee represents and warrants that, as of the Effective Date, it has not filed or registered, directly or indirectly, through any of its Affiliates or Third Party, in any country whatsoever, any designation, including as a trademark, in any International Classes, a company name, trade name, shop sign, domain name, incorporating the designations "WAKIX", "WAKIREM" or "BIOPROJET", that would be identical to the Trademarks or the Bioprojet trade name or likely to create a risk of confusion with the same in the mind of the consumers.

- (b) Licensee acknowledges that (i) nothing in this Agreement shall be construed as granting Licensee any right whatsoever (including any right of ownership) in any of the Trademarks or the Bioprojet trade name, in existence now or thereafter within and outside the Territory, and (ii) the Licensor is sole owner of all proprietary rights and interest in and to the Trademarks and the Bioprojet trade name.
- (c) Licensee undertakes never to challenge, oppose or seek cancellation of the Trademarks and/or the Bioprojet trade name, or any other trademark or trade name of the Licensor and/or Bioprojet or application filed by the Licensor and/or Bioprojet incorporating the designations "WAKIX", "WAKIREM" and/or "BIOPROJET".
- (d) Licensee undertakes, during the Term of this Agreement never to file or register directly or indirectly, through any of its Affiliates or Third Party, in any country whatsoever, any designation, including as a trademark, in any International Classes, a company name, trade name, shop sign, domain name, incorporating the terms "WAKIX", "WAKIREM" and/or "BIOPROJET", that would be identical to the Trademarks or the Bioprojet trade name or likely to create a risk of confusion with the same in the mind of the consumers.

7. <u>Termination and Effect Thereof.</u>

- (a) This Agreement shall terminate automatically upon termination of the L&C Agreement.
- (b) On the termination or expiration of this Agreement, all the rights of Licensee hereunder to use the Trademarks and the Bioprojet trade name shall terminate and automatically revert to Licensor and Licensee shall cease to use the same except as expressly permitted pursuant to Section 14.2 of the L&C Agreement. Licensee shall take all such steps as Licensor may reasonably request to give effect to the termination of the license to the Trademarks and the Bioprojet trade name in the Territory and to record any documents that may be required to evidence the termination of such license and transfer to Licensor of all rights, registrations, recordations and the like for such Trademarks and/or trade name.
- 8. Property of Licensor; Maintenance of Trademarks; Recordation of Licenses. To the extent any rights in and to the Trademarks and the Bioprojet trade name belonging to Licensor are deemed to accrue to Licensee, as a matter of law or otherwise, Licensee hereby assigns any and all such rights, at such time as they may be deemed to accrue, including all related goodwill, to Licensor. Licensor (or its designee) shall be responsible for filing, registering, renewing and maintaining at Licensor's sole cost and expense and in its own name (to the extent permitted by applicable law), appropriate registrations for the Trademarks and/or Bioprojet trade name in the Territory. Any necessary recordation of the Agreement with governmental agencies in the Territory shall be performed by Licensee at its sole cost and expense. If the Licensor intends to allow any of the Trademarks to lapse, the Licensor shall notify the Licensee and provide them with at least thirty (30) days' notice and offer to assign such Trademarks to the Licensee for consideration to be agreed on an arm's length basis between the Parties.
- 9. <u>Indemnification</u>. Subject to the other indemnification mechanisms set forth in the L&C Agreement, which shall prevail in case of conflict with this Section, Licensor hereby

indemnifies Licensee and its subsidiaries and affiliates, and the officers, directors, shareholders, principals, employees, agents and representatives of each of the foregoing, and their respective successors and permitted assigns individually and in the aggregate, against and hold each and all of them harmless from any and all claims, losses, liability, damages, costs and expenses (including reasonable attorneys' and accountants' fees and expenses) to the extent arising from Licensee's use of the Trademarks. The provisions of this Section and the obligations of Licensee set forth herein shall survive termination of this Agreement.

- 10. Applicable Law, Jurisdiction. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement and resolution of all disputes and any remedies relating thereto, shall be governed by and construed and enforced in accordance with the laws of England and Wales, without reference to its conflict of law principles. Any dispute, controversy, difference or issue which may arise between the Parties, unless settled by mutual consultation in good faith, shall be submitted to arbitration for final resolution in the conditions set forth in the L&C Agreement. The Parties agree and acknowledge that all prior discussions concerning the subject matter of this Agreement are merged into and superseded hereby, and there are no oral or other undertakings.
- 11. <u>Severability.</u> In the event that any term or provision of this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein
- 12. <u>Entire Agreement</u>. This Agreement, together with the L&C Agreement, represents the entire understanding between the Parties hereto with respect to the subject matter hereof and supersedes all previous representations, understandings or agreements, oral or written, between the Parties with respect to the subject matter hereof. This Agreement cannot be modified except by a written instrument signed by the Parties hereto. Any discrepancy between this Agreement and the L&C Agreement shall he governed by the L&C Agreement.
- 13. <u>Further Assurances</u>. The Parties shall prepare and execute such further documentation and perform such further actions, including the recordation of such documentation with appropriate authorities, as may be reasonably requested by either of the Parties hereto, to evidence or give effect to this Agreement or to enforce the Trademarks.
- 14. <u>Binding Agreement</u>. This Agreement will be binding upon, and inure to the benefit of, the Parties and their respective successors, permitted sub-licensees, assigns and transferees, and agents.
- 15. <u>Assignability</u>. This Agreement shall not be assignable by either Party to any Third Party hereto without the written consent of the other Party hereto. Either Party shall have the right to assign this Agreement to an Affiliate (as defined in the L&C Agreement), with the prior written consent of the other Party hereto (which shall not be unreasonably withheld, conditioned or delayed); provided that the assigning Party guarantees the performance of this Agreement by such Affiliate and such Affiliate agrees in a writing delivered to the non-assigning Party to assume all of the rights and obligations of the assigning Party under this Agreement; and further provided that

if the non-assigning Party reasonably believes such assignment could result in material adverse tax consequences to the non-assigning Party, the non-assigning Party shall have no obligation to consent to the proposed assignment. Subject to the foregoing, this Agreement shall inure to the benefit of each Party hereto, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 16 shall be null and void.

- 16. Confidentiality. Section 10 of the L&C Agreement shall apply mutatis mutandis to this Agreement.
- 17. <u>Section Headings</u>. Section headings are included solely for convenience, are not considered to be a part of this Agreement and are not intended to be full and accurate descriptions of the contents of such provisions.
- 18. <u>Notices</u>. All notices, requests, consents, demands, approvals and other communications, including the service of process, hereunder shall be deemed to have been duly given, made or served if in writing and delivered personally or sent by overnight carrier that requires the addressee to acknowledge receipt thereof to the respective Parties to this Agreement as set forth in the L&C Agreement. Informal communications between the Parties may be properly transmitted by e-mail.
- 19. <u>Variation</u>. No variation of this Agreement shall be valid or effective unless it is in writing, refers to this Agreement and is duly signed or executed by, or on behalf of, each Party.
- 20. <u>No Partnership or Agency.</u> Nothing in this Agreement constitutes, or shall be deemed to constitute, a partnership between the Parties nor make any Party the agent of another Party.
 - 21. Survival. Provisions which by their terms or intent are to survive termination of this Agreement shall do so.
- 22. <u>Waiver</u>. No failure, delay or omission by either Party in exercising any right, power or remedy provided by law or under this Agreement shall operate as a waiver of that right, power or remedy, nor shall it preclude or restrict any future exercise of that or any other right or remedy. No single or partial exercise of any right, power or remedy provided by law or under this Agreement shall prevent any future exercise of it or the exercise of any other right, power or remedy.
- 23. <u>Third Party Rights</u>. No one other than a Party to this Agreement, their successors and permitted assignees, shall have any right to enforce any of its provisions.
- 24. <u>Counterparts</u>. This Agreement may be executed in multiple counterparts, each of which shall be regarded for all purposes as an original, and such counterparts shall constitute a single document. The Parties may also exchange signatures (in counterparts) by facsimile or e-mail transmission, which signatures shall be deemed to be original, valid and binding.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

BIOPROJET EUROPE, LTD.

By: /s/ Jean-Guillaume Lecomte

Name: Jean-Guillaume Lecomte

Title: Director

BIOPROJET SOCIETE CIVILE DE RECHERCHE

By: /s/ Jean-Marie Lecomte

Name: Jean-Marie Lecomte

Title: CEO

HARMONY BIOSCIENCES, LLC

By: /s/ John Jacobs
Name: John C. Jacobs

Title: Chief Executive Officer

Exhibit A

Trademarks

COUNTRIES / TRADEMARKS

26 juin 2017

Country United States of America

Trademark	Registered Owner	Classes	No / Date Application	No / Date Registration	Status	Next Renewal Date
WAKREM	BIOPROJET EUROPE	5	87377316		Pending	
	LTD		20 mars 2017			
WAKIX	BIOPROJET EUROPE	5	1211316	4600400	Registered	25-juin-2024
	LTD		25 juin 2014	03 Novr. 2015		

Exhibit B

Brand Guidelines

[***]

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MANAGEMENT SERVICES AGREEMENT

This **MANAGEMENT SERVICES AGREEMENT** (this "**Agreement**"), dated as of September 22, 2017 (the "**Effective Date**"), is by and among Paragon Biosciences, LLC, a Delaware limited liability company (the "**Management Company**"), Harmony Biosciences, LLC, a Delaware limited liability company (the "**Company**"), and, solely with respect to <u>Section</u> 6 herein, Jeffrey S. Aronin ("**Aronin**"). Capitalized terms used but not otherwise defined herein shall have the meanings set forth <u>Section 9</u> of this Agreement.

RECITALS

WHEREAS, the Company is party to that certain License and Commercialization Agreement, dated as of July 28, 2017, with Bioprojet Société Civile de Recherche (the "**License Agreement**") with respect to the commercialization by the Company in the United States and its territories, commonwealths and protectorates (including Puerto Rico) (the "**Territory**") of that certain product currently known as Wakix[®] (the "**Product**");

WHEREAS, the Management Company, together with its Affiliates, provides management, technical, administrative and support services in connection with the registration and commercialization of pharmaceutical products in the Territory;

WHEREAS, the Company desires to engage the Management Company to provide and arrange certain management, technical, administrative and support services in connection with the commercialization by the Company of the Product in the Territory and the performance by the Company of its obligations under the License Agreement; and

WHEREAS, the Company and the Management Company each desires to enter into this Agreement to set forth their mutual understandings and agreements with respect to the matters set forth herein.

AGREEMENTS

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

1. Appointment as Management Company. The Management Company is hereby retained by the Company to provide certain management and advisory services and other assistance as may be requested by the Company and agreed to by the Management Company from time to time, including, but not limited to, the services described on Schedule A hereto (the "Management Services"). The Management Company shall use commercially reasonable efforts to provide the Management Services in a manner consistent with industry standards for such Management Services, as employed by biotechnology and/or pharmaceutical companies that are similarly situated to the Company. The Management Company shall primarily focus on providing senior-level strategic and tactical guidance, oversight, advice and support services with respect to pharmaceutical-related matters, and assistance to the Company in developing key in-house

capabilities. In this capacity, the Management Company will commit significant management resources to the Company, with the Management Company's initial leadership team including Jeff Aronin, Pat Morris, Tim Cunniff, Babar Ghias, Spiro Katerinis and such other individuals deemed appropriate by the Management Company to facilitate the Company's business plan and objectives. It is the parties' intent and expectation that the Management Services will include guidance, oversight, advice and support with respect to key activities necessary or useful to enhance the Company's ability to obtain regulatory approval for the Product in the Territory.

2. Compensation.

- (a) In exchange for services to be provided by the Management Company hereunder, the Company shall pay the Management Company, and the Management Company shall be entitled to receive from the Company, a monthly management fee (the "Management Fee") in the amount of \$333,333.33 with respect to each calendar month of the Term prior to the third (3rd) anniversary of the Effective Date and in the amount of \$166,666.66 with respect to each calendar month of the Term following the third (3rd) anniversary of the Effective Date. The Management Fee for the first calendar month of the Term shall be payable within two (2) business days following the Effective Date. Thereafter, the Management Fee payable with respect to each calendar month shall be paid not later than the fifth day of such calendar month by recurring ACH transfer (established as an automatic feature with the Company's bank) provided that the Management Company delivers a written invoice to the Company at least ten (10) days prior to the first day of such calendar month. If the Management Company fails to deliver a written invoice prior to the first day of such calendar month, then the Company shall pay the Management Fee with respect to a given calendar month no later than thirty (30) days after the receipt of a written invoice from Management Company with respect to the Management Services to be provided (or that were provided) in such calendar month, by wire transfer of immediately available funds to an account or accounts previously specified in writing by the Management Company. The Management Fee shall be prorated based on the number of days in any partial calendar month during the Term. If the Management Fee decreases on any day other than the first day of a calendar month, then the Management Fee payable with respect to the applicable calendar month for the period prior to such decrease shall be prorated based on the number of days in such calendar month prior to such decrease, and the Management Fee payable with respect to such calendar month for the period following such decrease shall be prorated based on the number of days in such calendar month following such decrease.
- (b) In addition to the Management Fee, the Company shall pay to the Management Company, and the Management Company shall be entitled to receive from the Company, an additional payment in the amount of \$4,000,000.00, which shall be paid within one business day following the Effective Date by wire transfer of immediately available funds to an account or accounts previously specified in writing by the Management Company.

Except as contemplated by this Agreement, the Management Company shall not be entitled to receive from the Company any other compensation or remuneration in consideration for its services to the Company.

3. Expenses. The Management Company shall bear the cost of its out-of-pocket expenses incurred in connection with the services performed hereunder, and shall not be entitled to reimbursement from the Company.

4. Effective Period of Agreement and Amendments.

- (a) The term of this Agreement (the "**Term**") shall begin on the Effective Date and end on the sixth (6th) anniversary thereof; provided, that the Term may be terminated prior to the expiration thereof (i) by the Management Company at any time for any reason or no reason by giving the Company written notice of such termination at least one hundred eighty (180) days in advance of such termination date (unless such notice is waived by the Company in its sole discretion, in which case such termination shall be effective as of the date of such waiver), (ii) by the Company for Cause by giving the Management Company written notice of such termination, (iii) by the Company upon the consummation of an IPO by giving the Management Company written notice of such termination; provided, however, that if any termination under this subsection (iii) occurs prior to the end of the fourth year following the Effective Date, then within thirty (30) days following such termination the Company shall pay to the Management Company an amount equal to 100% of all remaining amounts to be paid to the Management Company under this Agreement between the date of such termination and the end of such fourth year, and (iv) by the Company upon written notice to the Management Company if a Sale of Harmony has been consummated prior the consummation of an IPO; provided, however, that if such Sale of Harmony results in payment to the Investors of an aggregate amount equal to or greater than the Series A Preferred Return (as defined in the A&R Certificate of Incorporation) (after payment of all costs and expenses incurred by Holdings in connection with such Sale of Harmony, including the payment of amounts payable to the Management Company pursuant to this Section 4(a)), then within thirty (30) days following such termination the Company under this Agreement.
- (b) Any amendment to this Agreement shall be in writing and shall be approved and executed by both the Management Company and the Company; <u>provided</u>, <u>however</u>, that such approval of the Company shall be subject to the authorization and approval of the Board. <u>Sections 5</u>, <u>6</u>, <u>7</u>, <u>11</u>, <u>12</u>, <u>15</u> and <u>16</u> of this Agreement shall survive the expiration or termination of the Term.
- 5. <u>Business Opportunity</u>. During the Term and for a period of two (2) years thereafter, if the Management Company is formally offered an opportunity to pursue a potential transaction to acquire, license or obtain a pharmaceutical product in the Field (as defined in the License Agreement) or to acquire a majority ownership interest in a Person that sells pharmaceutical products in the Field (but not including a minority investment) that the Management Company reasonably believes is, or may be, within the scope of the business and investment objectives of the Company and would be beneficial to the business of the Company and that the Management Company desires to pursue (each an "Opportunity"), then the Management Company shall present such Opportunity to the Board. The Board shall determine whether to pursue any such Opportunity and shall make such determination within a reasonable period of time; provided, that if the Board determines not to pursue any such Opportunity, then the Management Company and its Affiliates will not separately pursue such Opportunity.

- **6.** Restrictive Covenants. During the Term, the Management Company and Aronin will have access to the most sensitive and most valuable trade secrets, proprietary information and other confidential information of the Company, including pharmaceutical studies and reports, management reports, marketing studies, marketing plans, business plans, financial statements, feasibility studies, financial, accounting and statistical data, price and cost information, customer lists, contracts, policies and procedures, internal memoranda, reports and other materials or records of a proprietary or confidential nature (collectively, "Confidential Information"), which constitute valuable business assets of the Company and its Affiliates, and the use, application or disclosure of such Confidential Information will cause substantial and possibly irreparable damage to the business and asset value of the Company. Therefore, as an inducement for the Company to enter into this Agreement and to protect the Confidential Information and other business interests of the Company, Aronin and the Management Company each agree to be bound by the restrictive covenants contained in this Section 6.
 - (a) **Confidential Information**. After the date of this Agreement, Aronin and the Management Company will, and, in the case of the Management Company, will cause its Affiliates, directors, managers, officers, equityholders, employees, agents, successors and permitted assigns to, keep confidential and not disclose to any other Person or use for his or its own benefit, as applicable, or the benefit of any other Person any Confidential Information; <u>provided</u>, <u>however</u>, that the obligations under this <u>Section 6(a)</u> will not apply to Confidential Information that (i) is or becomes generally available to the public without breach of the commitments contemplated by this <u>Section 6(a)</u>, (ii) was available to Aronin or the Management Company or its Affiliates, directors, managers, officers, equityholders, employees or agents on a non-confidential basis prior to the date of this Agreement or (iii) is required to be disclosed by any Law or Order; <u>provided</u>, that as soon as practicable prior to any such disclosure, Aronin and/or the Management Company, as applicable, shall give the Company prompt written notice of such disclosure to enable the Company to seek a protective order or otherwise preserve the confidentiality of such information.
 - (b) **Covenant Not to Compete.** For the period beginning on the Effective Date and ending on the second anniversary of the date on which all of Aronin and the Management Company and its Affiliates (including, for the avoidance of doubt, Marshman Fund Trust II) cease to own any Stock and any other equity interest in Holdings (the "**Restricted Period**"), Aronin and/or the Management Company, as applicable, will not, directly or indirectly, own, manage, operate, join, control, finance or participate in, or participate in the ownership, management, operation, control or financing of, or be connected as an owner, investor, partner, joint venturer, director, limited liability company manager, employee, independent contractor, consultant or other agent of, any Person or enterprise that is developing a pharmaceutical product in the sleep field, or owns, licenses, sells, or markets such a product anywhere in or with respect to the Territory.

- (c) During the Restricted Period, Aronin and the Management Company will not, directly or indirectly:
- i. solicit or induce or attempt to solicit or induce (including by recruiting, interviewing or identifying or targeting as a candidate for recruitment) any officer or personnel (whether engaged as an employee or independent contractor) of the Company (a "**Business Associate**"), to terminate, restrict or hinder such Business Associate's association with the Company or interfere in any way with the relationship between such Business Associate and the Company; <u>provided</u>, <u>however</u>, that after the termination or expiration of this Agreement, general solicitations published in a journal, newspaper or other publication or posted on an internet job site and not specifically directed toward Business Associates will not constitute a breach of the covenants in this <u>Section 6(c)</u>; or
- ii. hire or otherwise retain the services of any Business Associate as officer, employee, independent contractor, licensee, consultant, advisor, agent or in any other capacity, or attempt or assist anyone else to do so.
- (d) **Scope of Covenants; Equitable Relief.** Aronin and the Management Company acknowledge and agree that (i) the restrictive covenants contained in this Section 6 and the territorial, time, activity and other limitations set forth herein are commercially reasonable and do not impose a greater restraint than is necessary to protect the goodwill and legitimate business interests of the Company and its businesses, (ii) any breach of the restrictive covenants in this Section 6 will cause irreparable injury to the Company and that actual damages may be difficult to ascertain and would be inadequate, (iii) if any breach of any such covenant occurs, then the Company will be entitled to seek injunctive relief in addition to such other legal and equitable remedies that may be available (without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement) and (iv) Aronin and the Management Company hereby waive the claim or defense that an adequate remedy at law exists for such a breach.

7. Inventions.

(a) The Management Company agrees that all Inventions will be the sole and exclusive property of Company. The Management Company hereby irrevocably transfers and assigns to the Company, and agrees to irrevocably transfer and assign to the Company, all right, title and interest throughout the world in and to any and all pharmaceutical products, inventions, improvements, techniques, know-how, algorithms, processes, designs, technology, information, software, illustrations, artwork, documentation, photographs, trademarks, materials, original works of authorship, biological or chemical specimens or samples, databases and trade secrets that the Management Company may solely or jointly make, conceive or develop or reduce to practice during the Term, that result from or arise out of the Services or that are aided by the use of time, materials, facilities, trade secrets, or proprietary information of the Company, whether or not they are eligible for patent, copyright, mask work, trade secret, trademark or other legal protection (collectively, the "Inventions"). Without limiting the generality of the foregoing, the Company will be the sole owner of any regulatory dossiers and regulatory filings for the Product or other products of the Company that are prepared and/or filed by the Management Company pursuant to the Agreement.

- (b) The Management Company hereby irrevocably transfers and assigns to the Company, and agrees to irrevocably transfer and assign to the Company, all right, title and interest throughout the world to any and all intellectual property rights in or associated with such Inventions, including without limitation all patents, copyrights, trademark rights, trade dress rights and trade secret rights, and applications for any of the foregoing (collectively "Intellectual Property Rights"). The Management Company will promptly make full written disclosure to the Company of all Inventions and will have all Inventions in trust for the sole right and benefit of the Company. All copyrightable works made by the Management Company during the Term are and will be treated as "works made for hire" to the greatest extent permitted by applicable law. At the Company's request and expense, during and after the term of this Agreement, the Management Company will assist and cooperate with the Company in all respects and will cause all Management Company personnel to assist and cooperate with the Company in all respects, and will execute documents and will cause all Management Company personnel to execute documents, and will take such further acts reasonably requested by the Company to enable the Company to acquire, transfer, maintain, perfect and enforce its Intellectual Property Rights and other legal protections for the Inventions. The Management Company hereby appoints the officers of the Company as the Management Company's attorney-in-fact to execute documents on behalf of the Management Company for this limited purpose.
- (c) The assignments by the Management Company to the Company of Inventions hereunder includes (i) all rights of attribution, paternity, integrity, disclosure and withdrawal, (ii) any rights that the Management Company may have under the Visual Artists Rights Act of 1990 or similar federal, state, foreign or international laws or treaties, and (iii) all other rights throughout the world sometimes referred to as "moral rights" (collectively "Moral Rights"). To the extent that Moral Rights cannot be assigned under applicable law, the Management Company hereby waives such Moral Rights to the extent permitted under applicable law and consents to any and all actions of the Company that would otherwise violate such Moral Rights.
- (d) To the extent that the Management Company owns or controls (presently or in the future) any patent rights, copyright rights, mask work rights, trade secret rights, or any other intellectual property or proprietary rights that may block or interfere with, or may otherwise be required for, the exercise by the Company of the rights assigned to the Company under this Section 7 (collectively, "Related Rights"), the Management Company hereby grants or will cause to be granted to the Company a non-exclusive, royalty-free, irrevocable, perpetual, transferable, worldwide license (with the right to sublicense) to make, have made, use, offer to sell, sell, import, copy, modify, create derivative works based upon, distribute, sublicense, display, perform and transmit any products, software, hardware, methods or materials of any kind that are covered by such Related Rights, to the extent necessary to enable the Company to exercise all of the rights assigned to the Company under this Section 7.

8. Warranties.

(a) **No Pre-existing Obligations**. The Management Company represents and warrants that the Management Company has no pre-existing obligations or commitments

(and will not assume or otherwise undertake any obligations or commitments) that would be in conflict or inconsistent with or that would hinder the Management Company's performance of its obligations under <u>Section 1</u> of this Agreement.

(b) **Agreements with Consultant Personnel**. The Management Company represents and warrants that all Management Company personnel who perform Services are and will be bound by written agreements with the Management Company under which: (i) the Management Company owns or is assigned exclusive ownership of all Inventions, including all Intellectual Property Rights therein; and (ii) the Management Company personnel agree to limitations on the use and disclosure of Confidential Information no less restrictive than those provided in <u>Section 6</u>.

9. <u>Definitions</u>.

"Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. As used herein, the term "control" means: (i) the power to vote at least fifty percent (50%) of the voting power of a Person, or (ii) the possession, directly or indirectly, of any other power to direct or cause the direction of the management and policies of such a Person, whether through ownership of voting securities, by contract or otherwise.

"A&R Certificate of Incorporation" means the Amended and Restated Certificate of Incorporation of Holdings dated as of September 21, 2017.

"Board" means the board of directors of Holdings.

- "Cause" shall exist with respect to the Management Company if:
- (i) the Management Company or Aronin has been convicted of or pleaded *nolo contendere* in respect of any felony or any other crime involving fraud or dishonesty with respect to the Company or any of its Affiliates involving amounts in excess of \$25,000;
- (ii) the Management Company has substantially and repeatedly failed to perform its duties and responsibilities under this Agreement, which failure continues for at least thirty (30) days following the Management Company's receipt of written notice thereof specifying in reasonable detail the action or omission that constitutes such failure;
- (iii) Aronin has engaged in consistent alcohol abuse or illegal drug use that interferes with the performance of the Management Company's duties hereunder; or
- (iv) the Management Company or Aronin has engaged in any act or omission constituting willful misconduct that has caused material injury to the Company.

"Holdings" means Harmony Biosciences II, Inc., a Delaware corporation.

"**Investors**" means each of the stockholders listed on Schedule A of that certain Investors' Rights Agreement, dated as of the Effective Date, by and among Holdings, the Investors and the Key Holders (as defined therein) (the "**Investors' Rights Agreement**").

"IPO" means Holdings' first underwritten public offering of its Common Stock under the Securities Act.

"Law" means any federal, state, local, municipal, foreign, international, multinational or other constitution, statute, law, rule, regulation, ordinance, code, principle of common law or treaty.

"Order" means any order, injunction, judgment, decree, ruling, assessment or arbitration award of any government authority or arbitrator.

"**Person**" means an individual, a partnership, a limited liability company, a corporation, an association, a joint stock company, a trust, a joint venture, an unincorporated organization, investment fund, any other business entity and a governmental entity or any department, agency or political subdivision thereof.

"Sale of Harmony" means a transaction or series of related transactions in which an independent third Person, or an independent group of related third Persons, acquires (whether by merger, consolidation, sale, exclusive license, exclusive marketing or distribution, recapitalization, transfer, exchange or other distribution or disposition) from stockholders of Holdings shares representing more than fifty percent (50%) of (i) the issued and outstanding shares of capital stock of Holdings or any of its subsidiaries (provided that, in the case of such sale of the shares of capital stock of any of Holdings' subsidiaries, the shares of capital stock of such subsidiary or subsidiaries constitute substantially all of the assets of Holdings and its subsidiaries, taken as a whole), or (ii) the assets of Holdings and its subsidiaries, taken as a whole.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Stock" means, collectively, the Series A Preferred Stock (the "Preferred Stock") and the Common Stock of Holdings (the "Common Stock").

10. <u>Notices</u>. All notices and other communications hereunder shall be in writing and shall be (a) delivered personally, (b) sent by facsimile or overnight mail, postage prepaid, or (c) sent by e-mail, with electronic, written or oral confirmation of receipt, addressed as follows (or at such other address or number for a party as shall be specified by like notice):

if to the Management Company, to:

Paragon Biosciences, LLC [Address]

if to the Company, to:

Harmony Biosciences, LLC [Address]

Any such notice shall be deemed to be delivered, given and received for all purposes as of: (i) the date so delivered, if delivered personally, (ii) upon receipt, as confirmed by a confirmation page if sent by facsimile, or by electronic, written or oral confirmation of receipt if sent by email or (iii) on the date of receipt or refusal indicated by the overnight carrier, if sent by overnight mail, postage and charges prepaid and properly addressed.

11. Liability; Indemnification.

- (a) Notwithstanding and in addition to any rights afforded the Company and any of its present or former partners, shareholders, members, directors, officers, employees or agents (collectively, the "Company Indemnitees"), the Management Company shall indemnify and hold harmless each Company Indemnitee from and against any loss, expense or damage payable to a third party by such Company Indemnitee as a result of any claim, action or proceeding brought against a Company Indemnitee by such third party, including any judgment, award, settlement, reasonable attorneys' fees and other costs or expenses incurred in connection with the defense of such claim, action or proceeding, to the extent arising primarily from (i) the material breach of this Agreement by the Management Company or (ii) any fraud, bad faith or gross negligence of the Management Company or any Management Company Indemnitee (as defined below).
- (b) Notwithstanding and in addition to any rights afforded the Management Company and any of its present or former partners, shareholders, members, directors, officers, employees or agents (collectively, the "Management Company Indemnitees"), the Company shall indemnify and hold harmless each Management Company Indemnitee from and against any loss, expense or damage payable to a third party by such Management Company Indemnitee as a result of any claim, action or proceeding brought against a Management Company Indemnitee by such third party, including any judgment, award, settlement, reasonable attorneys' fees and other costs or expenses incurred in connection with the defense of such claim, action or proceeding, to the extent arising from the Management Company's performance of the Management Services; provided, however, that Company shall have no indemnification obligations hereunder to the extent such loss, expense or damage results primarily from the material breach of this Agreement by the Management Company or fraud, bad faith or gross negligence of the Management Company or any Management Company Indemnitee.
- (c) If any Management Company Indemnitee or Company Indemnitee (each, an "**Indemnitee**") learns of a third party claim for which it intends to seek indemnification hereunder, then such Indemnitee shall give prompt written notice thereof to the indemnifying party and shall permit the indemnifying party to defend and/or settle such

third party claim, so long as it does so diligently and in good faith; <u>provided</u>, that any delay in providing such notice shall not limit the rights of indemnification of such Indemnitee under this Agreement except to the extent such delay prejudices the indemnifying party's ability to defend such claim. If determined by the indemnifying party, any such indemnification may be paid by the indemnifying party in advance of the final disposition of any such action, proceeding or claim upon receipt of an undertaking by or on behalf of such Indemnitee seeking advancement to repay the amount advanced should it ultimately be determined that such Indemnitee was not entitled to be indemnified hereunder.

- (d) NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT TO THE CONTRARY, (i) NEITHER PARTY SHALL HAVE ANY LIABILITY FOR CONSEQUENTIAL, PUNITIVE, INDIRECT, SPECIAL, EXEMPLARY OR INCIDENTAL DAMAGES, TO THE OTHER PARTY (INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS, REVENUES, DATA AND/OR USE), ARISING OUT OF OR IN CONNECTION HEREWITH OR THE PERFORMANCE BY THE MANAGEMENT COMPANY OF THE SERVICES, AND (ii) IN NO EVENT SHALL THE AGGREGATE LIABILITY OF THE MANAGEMENT COMPANY UNDER THIS AGREEMENT EXCEED THE AGGREGATE AMOUNT PAID BY THE COMPANY TO THE MANAGEMENT COMPANY UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE OCCURRENCE OF THE EVENT GIVING RISE TO THE ALLEGED DAMAGES.
- 12. <u>Structural Indemnification</u>. The Management Company hereby agrees to defend, indemnify and hold harmless the Company against all claims, expenses, costs, damages, liabilities and losses (including attorneys' fees, judgments, fines, excise taxes or penalties) incurred or suffered by the Company (or one or more of the Company's Affiliates) as arising out of or resulting from any taxes imposed upon the Company related to the treatment of any employee or service provider of the Management Company for purposes of tax reporting or tax withholdings and/or the status of any employee of the Management Company as an employee of the Company.
- 13. <u>Insurance</u>. During the Term, the Company shall obtain and maintain at its own expense, standard directors and officers liability insurance policy ("**D&O Policy**"), which D&O Policy shall list each of the Management Company and Aronin as an additional insured. At all times during the engagement of the Management Company and for a period of six (6) years thereafter, the Company shall maintain the D&O Policy in amounts not less than those in effect on the Effective Date.
- **14.** Relationship of the Parties. Nothing contained herein shall be construed to place the parties in the relationship of employer/employee, partners or joint venturers. Except as otherwise provided in this Agreement, the Company shall have no power to obligate or bind the Management Company in any manner whatsoever. The Management Company shall not have any power to obligate or bind the Company in any manner whatsoever, other than as provided by this Agreement and pursuant to the exercise fits authority hereunder.
- **15. Non-Assignability and Delegation**. This Agreement shall not be assigned by either party hereto without the prior written consent of the other party; **provided**, **however**, that the

consent of the Company to any assignment of this Agreement shall be subject to the authorization and approval of the Board. Notwithstanding the foregoing, Company shall be permitted, without any requirement to obtain the Management Company's consent, to assign this Agreement (a) in part or in its entirety to an Affiliate of the Company or (b) in its entirety to the successor to all or substantially all of the assets or business of the Company to which this Agreement relates, whether by merger, acquisition, sale of stock, sale of assets, or otherwise. The Management Company shall perform the Management Services itself and shall not subcontract or delegate any of its rights or obligations under this Agreement without the prior written consent of the Company following the authorization and approval of the Board. Any and all contracts with third parties relating to Wakix® or other Company products will be between the Company and the applicable third party, except to the extent that the Company agrees in writing to allow the Management Company to directly contract with one or more third parties. Subject to the prohibitions contained in this Section 15, this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Company and the Management Company.

16. Governing Law. This Agreement, including its existence, validity, construction and operating effect, and the rights of each party hereto, shall be governed by and construed in accordance with the laws of the State of Illinois without giving effect to any conflicts or choice of laws provisions that would cause the application of the domestic substantive laws of any other jurisdiction.

17. Miscellaneous

- (a) This Agreement constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and fully supersedes any and all prior or contemporaneous agreements or understandings between the parties hereto pertaining to the subject matter hereof.
- (b) If any provision of this Agreement as applied to any party or any circumstances is determined by an arbitrator or any court having jurisdiction to be void, unenforceable or inoperative as a matter of law, then such provision shall be modified to the greatest extent legally possible so that the intent of this Agreement may be legally carried out. If any one or more of the provisions contained herein, or the application thereof in any circumstances, is held void, unenforceable or inoperative as a matter of law in any respect or for any reason, then the validity, enforceability and operation of any such provision in every other respect and of the remaining provisions hereof shall not be in any way impaired or affected, it being intended that each party's rights and privileges shall be enforceable to the fullest extent permitted by law.
- (c) This Agreement may be executed in counterparts, any of which may be delivered via facsimile, *.pdf* or other forms of electronic delivery, each of which shall be deemed to be an original and all of which, taken together, shall constitute one agreement.

Signature Page Follows.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date first above written.

Management Company

PARAGON BIOSCIENCES, LLC

By: /s/ Jeffrey S. Aronin
Name: Jeffrey S. Aronin
Title: President and Secretary

Company

HARMONY BIOSCIENCES, LLC

By: /s/ Patrick J. Morris
Name: Patrick J. Morris
Title: General Counsel

Aronin solely with respect to Section 6 of this Agreement

By: /s/ Jeffrey S. Aronin
Name: Jeffrey S. Aronin

[Signature Page to Management Services Agreement]

Schedule A

- Senior-level strategic and tactical guidance and support
- Oversight, advice and support services relating to pharma-related matters, including:
 - Research & development and formulation
 - Preclinical
 - Clinical pharmacology
 - New indication clinical development
 - New indication project management
 - New indication regulatory
 - New indication quality assurance
 - Regulatory strategy
 - Advisory committee preparation
 - Human resources support services
 - Financial oversight
 - Financial infrastructure
 - Information technology infrastructure and technical support
 - Merger and acquisition strategy and tactical support
- Oversight, advice and support services relating to finance/accounting
- Legal oversight, services and support
- Accounting, finance, and commercial services

RIGHT OF USE AGREEMENT

This Right of Use Agreement ("Agreement"), effective as of November 1, 2019 (the "Effective Date"), is by and between Paragon Biosciences, LLC, a Delaware limited liability company ("Paragon"), and Harmony Biosciences, LLC, a Delaware limited liability company (the "Portfolio Company").

Recitals

WHEREAS, Paragon and the Portfolio Company are both engaged in the Healthcare industry.

WHEREAS, the Portfolio Company is one of Paragon's portfolio companies.

WHEREAS, there is benefit to both Paragon and the Portfolio Company for the Portfolio Company, together with current and future Paragon portfolio companies, to use office space in Paragon's Innovation Center located at 330 N. Wabash Street, Suite 3500, Chicago, Illinois 60611 (the "Paragon Innovation Center").

Agreement

In consideration of the foregoing recitals and the covenants and fees set forth herein and subject to the Terms & Conditions attached hereto and the Portfolio Company's Paragon Innovation Center rules and regulations as in effect during the Term ("Paragon's Rules & Regulations"), together with any Addenda hereto, Paragon shall grant the Portfolio Company a license to use on a non-exclusive basis, together with Paragon and other current and future Paragon portfolio companies, one or more offices in the Paragon Innovation Center (referred to herein as the "Office"), and the facilities and services of the Paragon Innovation Center (together with the Office, sometimes collectively referred to herein as the "accommodation"), upon and subject to the terms set forth below.

The basic terms of this Agreement are as follows:

TERM

The term of this Agreement shall commence on the Effective Date and end on December 31, 2020 (the "Initial Term"), subject to (a) early termination by either party for any or no reason on at least thirty (30) days' prior written notice and (b) automatic renewals for subsequent twelve (12) month periods (each, a "Renewal Term") in the event that neither party provides written notice of non-renewal to the other party at least thirty (30) days prior to the expiration of the Initial Term or Renewal Term, as the case may be. The "Term" of this Agreement shall mean the Initial Term and any Renewal Term, as the case may be.

PAYMENTS

On or before March 1, 2020, the Portfolio Company shall pay to Paragon one lump-sum payment of \$400,000, together with interest thereon which shall accrue from the Effective Date through the

date of payment hereunder at an interest rate of 3% per annum, compounded annually (based on a 365 day year), with respect to the Portfolio Company's allocation of Paragon's incremental operating expenses incurred to develop the Paragon Innovation Center.

During the Term, the Portfolio Company shall pay to Paragon \$20,321 per calendar month (which amount may be increased or decreased from time to time by mutual written agreement of the parties) (the "Monthly Office Charge"), payable on or before the 15th day of each such calendar month.

In addition, during the Term, the Portfolio Company shall pay to Paragon \$3,333.33 per calendar month for the Portfolio Company's allocated share of the Paragon Innovation Center daily operating expenses and utilities (which amount may be increased or decreased from time to time by mutual written agreement of the parties) (the "Monthly Operating Charge").

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

PARAGON BIOSCIENCES, LLC

By:

HARMONY BIOSCIENCES, LLC

/s/ Patrick J. Morris Patrick J. Morris Name:

EVP, Legal Affairs & GC Its:

/s/ John Jacobs By: John Jacobs Name: President & CEO Its:

TERMS & CONDITIONS

NATURE OF THE AGREEMENT:

- 1.1. This Agreement is the commercial equivalent of an agreement for an accommodation in a hotel. The Paragon Innovation Center remains Paragon's property and in Paragon's possession and control. The Portfolio Company acknowledges that this Agreement is a license agreement and creates no tenancy interest, leasehold estate or other real property interest with respect to the accommodation and shall not be deemed or construed in any way to create a partnership or relationship of landlord and tenant between the parties hereto. Use of workstations (offices, cubicles or other work spaces) is subject to availability and may change at Paragon's discretion. The Portfolio Company will not be guaranteed the same or dedicated space during the contract period. THE PORTFOLIO COMPANY HEREBY WAIVES ANY AND ALL NOTICES TO CURE (EXCEPT AS EXPRESSLY SET FORTH IN SECTION 4.1 HEREOF), VACATE OR QUIT THE OFFICE.
- 1.2. The Agreement is personal to the Portfolio Company and cannot be transferred or assigned to any other party, unless written request of such assignment is submitted to Paragon and Paragon agrees to such assignment, which will be at Paragon's sole discretion, and the Portfolio Company will not permit occupancy or use of any part of the Office or the Paragon Innovation Center by any persons other than the Portfolio Company, its agents and employees.
- 1.3. Subject to all Terms & Conditions, Paragon's Rules & Regulations and any Exhibits or Addenda hereto, Paragon is granting the Portfolio Company a license for the use of the accommodations specified in this Agreement. All utilities, including any telephones and IT/data connection(s) outlined in this Agreement, shall be provided to the accommodation without additional expense to the Portfolio Company.
- 1.4. In the event the Paragon Innovation Center is no longer available and Paragon is permanently unable to provide the accommodations at the Paragon Innovation Center as stated in this Agreement, this Agreement will end and the Portfolio Company will only be obligated to pay monthly fees up to the date this Agreement ends and for the additional services the Portfolio Company has used..
- 1.5. Paragon can enter the Portfolio Company's Office at any time.
- 1.6. The Portfolio Company, its agents, employees and invitees, agree to abide by and observe the rules and regulations of Paragon's lease (the "Lease") with the owner of the building ("Landlord") in which the Paragon Innovation Center is located (the "Building"). The Portfolio Company's Agreement is subordinate to the Lease and to any other agreements to which the Lease is subordinate. This Agreement terminates, if not earlier, simultaneously with the expiration or sooner termination of the Lease for any reason. The Portfolio Company does not have any rights under the Lease (and all requests for building services shall be directed solely to Paragon), although the Portfolio Company will attorn to Landlord in such cases as may be required by the terms of the Lease or requested by Paragon or Landlord.
- 1.7. Paragon may assign this Agreement and the Portfolio Company agrees to accept any such assignee. Upon any such assignment, Paragon will be discharged from all liability hereunder.

- 1.8. All notices or other communications, except for service of process, must be in writing and shall be deemed duly given if delivered in person, or by a nationally-recognized commercial delivery service.
- 1.9. This Agreement shall be interpreted under the laws of the State of Illinois, without regard to conflicts of law. THE PORTFOLIO COMPANY HEREBY EXPRESSLY AND KNOWINGLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL IN ANY ACTION OR SUIT ARISING OUT OF THIS AGREEMENT OR THE PERFORMANCE OR NON-PERFORMANCE HEREOF.
- 1.10. The Portfolio Company must pay any reasonable and proper costs including legal fees that Paragon incurs in enforcing this Agreement.
- 1.11. This Agreement supersedes any prior agreement and embodies the entire agreement between the Portfolio Company and Paragon with respect to the subject matter hereof. This Agreement is an arm's length transaction between disinterested parties. There shall be no presumption of construction against the drafter of this Agreement.
- 1.12. The Portfolio Company and Paragon acknowledge and agree that neither Landlord, nor Landlord's agent, are parties to this Agreement and neither of them shall have any contractual liability or duty to the Portfolio Company by virtue of this Agreement, and that this Agreement shall not affect the rights and obligations between Paragon and Landlord.

2. USE AND OCCUPANCY:

- 2.1. The Portfolio Company agrees to use and occupy the Office solely for general office purposes. The Portfolio Company will only conduct business in the name as stated on the first page of this Agreement or some other name that Paragon has previously approved in writing.
- 2.2. The Portfolio Company agrees to comply, at its expense, with all applicable laws, orders, regulations and rules, pertaining to the use and occupancy of the Office, and the conduct of the Portfolio Company's business. The Portfolio Company must conduct its business so as not to interfere with the use of the Paragon Innovation Center by Paragon or other Paragon portfolio companies or their respective agents, employees or invitees, and the tenants of the Building and so as not to detract from the appearance of the Paragon Innovation Center. The Portfolio Company must comply with Paragon's safety standards, with Paragon's Rules & Regulations and the Building's rules and regulations. The Portfolio Company may not cause any nuisance or annoyance, cause the increase of insurance premiums Paragon has to pay, or cause loss or damage to Paragon (including damage to Paragon's reputation) or to Paragon's Landlord. The Portfolio Company acknowledges that (a) the terms of the this Section 2.2 are a material inducement in Paragon's execution of the Agreement and (b) any violation by the Portfolio Company of this Section 2.2 shall constitute a material default by the Portfolio Company hereunder, entitling Paragon to terminate this Agreement without further notice or procedure.
- 2.3. The Portfolio Company agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which the Portfolio Company is required to pay to any governmental authority (and, at Paragon's request, will provide evidence of such payment) and (ii) any taxes paid by Paragon to any governmental authority that are attributable to this Agreement, or the accommodations provided hereunder, including, without limitation, any gross receipts, rent and occupancy taxes, or tangible personal property taxes.

- 2.4. The Portfolio Company shall make no alterations or modifications in or to the Office, including, without limitation, affixing any signs or postings, and any door locks, without Paragon's prior written consent (which Paragon may grant or withhold in its sole discretion). In the event that alterations or modifications are made without Paragon's prior written consent, Paragon may, at Paragon's option, correct or remove the same at the Portfolio Company's sole cost and expense.
- 2.5. All keys and entry cards remain Paragon's property and shall not be duplicated or transferred to third parties. The loss of keys or cards must immediately be reported to Paragon. The Portfolio Company will be responsible for the cost of lost keys or cards as well as the cost of changing locks.
- 2.6. The Portfolio Company may not have any advertising of any type using the address of the Paragon Innovation Center without Paragon's prior written consent (which Paragon may grant or withhold in its sole discretion). Use of the address on business cards, websites, and other standard business practices are acceptable without written consent.
- 2.7. The Portfolio Company shall not, without Paragon's prior written consent (which Paragon may grant or withhold in its sole discretion), store or operate any computer equipment (except personal computer equipment) or any other large business machines, reproduction equipment, heating equipment, stove, mechanical amplification equipment, vending or coin-operated machines, refrigerator or coffee equipment.
- 2.8. The Portfolio Company may not install any cabling, IT or telecom connections without Paragon's prior written consent (which Paragon may grant or withhold in its sole discretion). As a condition of Paragon's consent, the Portfolio Company will permit Paragon to oversee any installations (for example, IT or electrical systems) to verify that such installations do not interfere with the use of the Paragon Innovation Center by Paragon, other the Paragon portfolio companies or Landlord. Paragon's consent may also be conditioned upon the payment of additional fees for installation and/or usage of such cabling, and/or the requirement that the Portfolio Company remove the cabling, etc. All cables in the ceiling or walls of the Paragon Innovation Center shall become Paragon's property.
- 2.9. The electrical current shall be used for ordinary lighting, powering personal computer equipment and small appliances only. If the Portfolio Company requires any special installation or wiring for electrical use, telephone equipment or otherwise, such wiring shall be done with Paragon's prior written approval, at the Portfolio Company's sole expense by a company approved by Paragon. The Portfolio Company shall not install or operate any equipment or machinery that requires a separate electrical circuit or consumes higher than normal and reasonable quantities of electricity.

3. LATE PAYMENTS

3.1. Paragon may charge the Portfolio Company a late payment charge equal to 10% of the arrearage with respect to any payment that is due and payable under this Agreement but is not paid when due.

4. DEFAULT AND TERMINATION:

- 4.1. Paragon may terminate this Agreement immediately by giving the Portfolio Company notice and without need to follow any additional procedures if: (a) the Portfolio Company becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they become due, or (b) the Portfolio Company is in breach of one of the Portfolio Company's obligations under this Agreement which cannot be cured or which Paragon has given the Portfolio Company notice to cure and which the Portfolio Company has failed to cure within thirty (30) days after written notice of such breach.
- 4.2. Paragon shall have the right to terminate the Agreement immediately if the Portfolio Company is or becomes (i) identified on the Specially Designated Nationals and Blocked Person List maintained by the U.S. Department of the Treasury Office of Foreign Assets Control or any similar list or (ii) a person, entity, or government with whom a citizen of the United States is prohibited from engaging in transactions by any trade embargo, economic sanction, or other prohibition of United States law, regulation or Executive order of the President of the United States.
- 4.3. If Paragon terminates the Agreement for any of the reasons described in the immediately preceding paragraphs, the Portfolio Company shall remain responsible for its outstanding obligations under this Agreement. The Portfolio Company may, in addition to any other obligations contained herein, be required to pay the amounts set forth in this Agreement for the remainder of the Term if Paragon had not so terminated this Agreement, or for a further period of three months, whichever is longer. In such event, Paragon may also take possession of the Office.
- 4.4. A waiver by either Paragon or the Portfolio Company of a breach (or series of breaches) of any covenant or obligation under this Agreement of the other party shall not be construed to be a waiver of any other covenant or obligation or of any subsequent breach of the same covenant or obligation. Notwithstanding the Paragon's reservation of any particular remedy hereunder, Paragon hereby reserves each and every remedy available at law or in equity in the event of a breach by the Portfolio Company hereunder.
- 4.5. Upon the expiration or termination of the Agreement, the Portfolio Company's right to occupy the Office and use the Paragon Innovation Center is revoked and the Portfolio Company will remove all of its property and return the Office and furniture in the same condition in which it was delivered to the Portfolio Company, subject to reasonable wear and tear. Any personal property left in the Office will be considered abandoned and Paragon may dispose of it without any liability to the Portfolio Company. All telephone and facsimile numbers are Paragon's property and cannot be transferred to the Portfolio Company at the expiration or termination of the Agreement.
- 4.6. For a period of 30 days after the expiration or termination of this Agreement, Paragon will redirect the Portfolio Company's mail upon receipt to an address provided in writing by the Portfolio Company at no charge and shall place a recorded message on the Portfolio Company's telephone line providing the Portfolio Company's new telephone number, as provided by the Portfolio Company in writing to Paragon, at no charge. Thereafter, Paragon shall have no obligation whatsoever to forward mail to the Portfolio Company or provide phone service.

- 4.7. If the Portfolio Company continues to occupy the Office after the Term of this Agreement has ended, the Portfolio Company will be responsible for any loss, claim or liability Paragon incur as a result of the Portfolio Company's failure to vacate on time. Paragon may, at Paragon's discretion, permit the Portfolio Company an extension subject to a surcharge on the Monthly Office Charge and the Monthly Operating Charge.
- 4.8. If the Paragon Innovation Center is made unusable in whole or in part by fire or other casualty or condemnation, Paragon may, at Paragon's option, either terminate this Agreement upon notice to the Portfolio Company, or repair the Paragon Innovation Center.

5. LIABILITY:

- 5.1. To the maximum extent permitted by applicable law, Paragon is not liable to the Portfolio Company in respect of any loss or damage the Portfolio Company suffers in connection with this Agreement or in connection with the services or the accommodations. Without limitation of the foregoing, Paragon is not liable for any loss or damage as a result of Paragon's failure to provide any service or accommodation under this Agreement as a result of mechanical breakdown, strike, termination of Paragon's Lease, or otherwise.
- 5.2. PARAGON WILL NOT UNDER ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA OR ANY CONSEQUENTIAL DAMAGES.
- 5.3. The Portfolio Company assumes all risk of loss with respect to the Portfolio Company's personal property and the Portfolio Company's agents, employees and invitees within the Paragon Innovation Center or the Building.
- 5.4. To the extent that the party sustaining a loss by fire or other casualty to its property is compensated by insurance, Paragon and the Portfolio Company will each waive all rights of recovery against the other party and no third party shall have any right of recovery.
- 5.5. Notwithstanding any term to the contrary, Paragon shall not be held liable to the Portfolio Company under this Agreement if Paragon is prevented from, or delayed in, performing Paragon's obligations under this Agreement or from carrying on Paragon's business by acts, events, omission or accidents beyond Paragon's reasonable control, including (without limitation): strikes, failure of a utility service or network; act of God, war, riot, civil commotion, disease or quarantine restrictions in compliance with any law or governmental rule, regulation or direction, accident, fire, floor or storm or default of suppliers or subcontractors. Paragon's obligation to perform its obligations under this Agreement shall be suspended during the period required to remove such force majeure event.
- 5.6. To the fullest extent permitted by law, the Portfolio Company agrees to hold Paragon and its other portfolio companies and their respective agents, employees, contractors, officers, directors and Landlord harmless from and against any and all claims of loss, costs, liability and expense, including reasonable attorneys' fees and disbursements (the "Claims"), arising from or alleged to arise from (a) any default by the Portfolio Company hereunder, (b) the use or occupancy of the Paragon Innovation Center by the Portfolio Company or any person claiming under the Portfolio Company, or (c) the Portfolio Company's negligence or the negligence of the Portfolio Company's agents, employees, contractors, officers or directors.

SECOND AMENDED AND RESTATED

INVESTORS' RIGHTS AGREEMENT

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SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

THIS SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "Agreement"), is made as of August 9, 2019, by and among Harmony Biosciences II, Inc., a Delaware corporation (the "Company"), and each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "Investor", and each of the stockholders of the Company and holders of warrants to acquire shares of capital stock of the Company listed on Schedule B hereto, each of whom is referred to herein as a "Key Holder".

RECITALS

WHEREAS, the holders of the Series A Preferred Stock and the Series B Preferred Stock are party with the Company and the Key Holders to that certain Amended and Restated Investors' Rights Agreement, dated as of January 8, 2018 (the "**Prior Agreement**");

WHEREAS, the Company and the Purchasers (as hereinafter defined) are parties to that certain Series C Preferred Stock Purchase Agreement of even date herewith (the "**Purchase Agreement**"), pursuant to which the Company has agreed to issue to the Purchasers (as defined in the Purchase Agreement), and the Purchasers have agreed to purchase, shares of Series C Preferred Stock (the "**Series C Issuance**");

WHEREAS, pursuant to Section 4 of the Prior Agreement, each of the holders of Series A Preferred Stock and Series B Preferred Stock, and each of the Key Holders (in their respective capacities as Major Holders), has a right of first offer in connection with the Series C Issuance (the "**Series C ROFR**");

WHEREAS, the Company, the Key Holders and the Investors desire to amend and restate the Prior Agreement in its entirety as set forth herein, and the holders of the Series A Preferred Stock, the holders of the Series B Preferred Stock and the Key Holders desire to waive the Series C ROFR;

WHEREAS, pursuant to Section 6.6 of the Prior Agreement, the Prior Agreement may be amended with the written consent of the Company and the holders of a majority of the shares of Preferred Stock then outstanding; and

WHEREAS, for purposes of this Agreement, to the extent any Person holds both shares of Preferred Stock and shares of Common Stock, such Person shall be treated as an Investor with respect to such shares of Preferred Stock and with respect to the shares of Common Stock issued or issuable upon conversion of such shares of Preferred Stock, and as a Key Holder with respect to such shares of Common Stock.

NOW, THEREFORE, the parties hereby agree as follows:

- 1. <u>Definitions</u>. For purposes of this Agreement:
- 1.1 "Affiliate" means, with respect to (a) any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such

Person or any venture capital fund or institutional investor now or hereafter existing that is controlled by one or more general partners, managing members or management companies of, or shares the same management company with, such Person, (b) in the case of a Fidelity Investor, an investment company registered under the Investment Company Act advised or sub-advised by Fidelity or any affiliated investment advisor of Fidelity, one or more mutual fund, pension fund, pooled investment vehicle or institutional client advised or sub-advised by Fidelity or any affiliated investment advisor of Fidelity, in each case, registered under the Investment Advisers Act of 1940, as amended and (c) Novo Holdings A/S ("Novo"), Novo Ventures (US), Inc. and any venture capital fund or other Person now or hereafter existing or formed for the purpose of making or evaluating investments in other Persons that is controlled by or under common control with Novo, and for the avoidance of doubt, shall not include any other affiliate of Novo.

- 1.2 "Common Stock" means shares of the Company's common stock, par value \$0.00001 per share.
- 1.3 "Damages" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.
- 1.4 "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.
 - 1.5 "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
- 1.6 "Excluded Registration" means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan, (ii) a registration relating to an SEC Rule 145 transaction, (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.
 - 1.7 "Fidelity" means Fidelity Management & Research Company.
 - 1.8 "Fidelity Investor" means any Investor advised or sub-advised by Fidelity.

- 1.9 **"Form S-1"** means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.
- 1.10 "Form S-3" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.
 - 1.11 "GAAP" means generally accepted accounting principles in the United States.
 - 1.12 "Holder" means any holder of Registrable Securities who is a party to this Agreement.
- 1.13 "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law, including, adoptive relationships, of a natural person referred to herein.
 - 1.14 "Initiating Holders" means, collectively, Holders who properly initiate a registration request under this Agreement.
 - 1.15 "Investment Company Act" means the Investment Company Act of 1940, as amended.
 - 1.16 "IPO" means the Company's first underwritten public offering of its Common Stock under the Securities Act.
 - 1.17 "Major Holder" means the Investors and the Key Holders.
- 1.18 "**Major Investor**" means each of Marshman, Valor, any Fidelity Investor, HBM Healthcare Investments (Cayman) Ltd. ("**HBM**"), Vivo, Novo Holdings A/S, venBio Global Strategic Fund II, L.P., Pivotal Alpha Limited and each Quantum/Aisling Investor.
 - 1.19 "Marshman" means Marshman Fund Trust II.
- 1.20 "Marshman Registrable Securities" means (i) the 50,000,000 shares of Common Stock held by Marshman as of the date hereof and (ii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, such shares.
- 1.21 "Marshman Warrant" means that certain Warrant to Purchase Common Stock of Harmony Biosciences II, Inc., issued by the Company to Marshman on September 22, 2017.
- 1.22 "New Securities" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

- 1.23 "Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.
- 1.24 "Preferred Stock" means, collectively, the Series A Preferred Stock, the Series B Preferred Stock and the Series C Preferred Stock.
- 1.25 "Quantum/Aisling Investors" means Aisling Capital IV, LP, QSIP LP and SCI Partners, LP, collectively.
- 1.26 "Registrable Securities" means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock, (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof, (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) and (ii) above and (iv) the Subordinate Registrable Securities; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.
- 1.27 "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.
 - 1.28 "SEC" means the Securities and Exchange Commission.
 - 1.29 "SEC Rule 144" means Rule 144 promulgated by the SEC under the Securities Act.
 - 1.30 "SEC Rule 145" means Rule 145 promulgated by the SEC under the Securities Act.
 - 1.31 "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- 1.32 "**Selling Expenses**" means all underwriting discounts, selling commissions and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in <u>Subsection</u> 2.6.
 - 1.33 "Series A Preferred Stock" means shares of the Company's Series A Preferred Stock, par value \$0.00001 per share.
 - 1.34 "Series B Preferred Stock" means shares of the Company's Series B Preferred Stock, par value \$0.00001 per share.

- 1.35 "Series C Preferred Stock" means shares of the Company's Series C Preferred Stock, par value \$0.00001 per share.
- 1.36 **"Subordinate Registrable Securities**" means collectively (a) Marshman Registrable Securities, (b) any Common Stock issued upon the exercise of the Marshman Warrant and the Valor Warrant and (c) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, such shares.
 - 1.37 "Valor" means Valor IV Pharma Holdings, LLC.
- 1.38 **"Valor Warrant**" means that certain Warrant to Purchase Common Stock of Harmony Biosciences II, Inc., issued by the Company to Valor on September 22, 2017.
 - 1.39 "Vivo" means collectively, Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P.
 - 2. Registration Rights. The Company covenants and agrees as follows:
 - 2.1 Demand Registration.
- (a) Form S-1 Demand. If, at any time after the effective date of the registration statement for the IPO, the Company receives a request from Holders of more than fifty percent (50%) of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement, then the Company shall (i) within ten (10) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders and (ii) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days following the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.
- (b) <u>Form S-3 Demand</u>. If, at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from any Holder that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holder, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days following the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.
- (c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this <u>Subsection 2.1</u> a certificate signed by the Company's

chief executive officer stating that in the good faith judgment of the Company's Board of Directors (the "**Board**") it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization or other similar transaction involving the Company, (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential or (iii) render the Company unable to comply with requirements under the Securities Act or the Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than one hundred twenty (120) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than twice in any twelve (12) month period; provided, further, that the Company shall not register any securities for its own account or that of any other stockholder during such one hundred twenty (120) day period other than an Excluded Registration.

- (d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(a)</u> (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, <u>provided</u> that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective, (ii) after the Company has effected five (5) registrations pursuant to <u>Subsection 2.1(a)</u> or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to <u>Subsection 2.1(b)</u>. The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(b)</u> (A) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, <u>provided</u> that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective or (B) if the Company has effected two (2) registrations pursuant to <u>Subsection 2.1(b)</u> within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this <u>Subsection 2.1(d)</u> until such time as the applicable registration statement has been declared effective by the SEC, unless the Holders of a majority of the Registrable Securities to be registered in such registration withdraw their request for such registration, elect not to pay the registration expenses therefor and forfeit their right to one (1) demand registration statement pursuant to <u>Subsection 2.6</u>, in which case such withdrawn registration statement shall be counted as "effec
- 2.2 <u>Company Registration</u>. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of <u>Subsection 2.3</u>, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or

withdraw any registration initiated by it under this <u>Subsection 2.2</u> before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with <u>Subsection 2.6</u>.

2.3 Underwriting Requirements.

- (a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, then they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Initiating Holders, subject to the reasonable approval of the Company. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Subsection 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting that are not Subordinate Registrable Securities shall not be reduced unless all other securities (including the Subordinate Registrable Securities) are first entirely excluded from the underwriting. To facili
- (b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to <u>Subsection 2.2</u>, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, that the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable) to the number of Registrable Securities owned by each selling Holder or in such other proportions

as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, (ii) the number of Registrable Securities included in the offering be reduced below twenty-five percent (25%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering or (iii) any Registrable Securities that are not Subordinate Registrable Securities be excluded from such underwriting unless all Subordinate Registrable Securities are first excluded from such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder", and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder", as defined in this sentence.

- (c) For purposes of <u>Subsection 2.1</u>, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in <u>Subsection 2.3(a)</u>, fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.
- 2.4 <u>Obligations of the Company</u>. Whenever required under this <u>Section 2</u> to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to sixty (60) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;
- (b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

- (c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;
- (d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; <u>provided</u> that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;
- (e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;
- (f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;
- (g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;
- (h) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents and properties of the Company, and cause the Company's officers, directors, employees and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;
- (i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and
- (j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

- 2.5 <u>Furnish Information</u>. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this <u>Section 2</u> with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.
- 2.6 Expenses of Registration. All expenses (other than Selling Expenses, which shall be borne by the Holders as provided herein) incurred in connection with registrations, filings or qualifications pursuant to Section 2, including all (a) registration, filing, and qualification fees, (b) printers' and accounting fees, (c) fees and disbursements of counsel for the Company and (d) the reasonable fees and disbursements of one (1) counsel for the selling Holders ("Selling Holder Counsel"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered in such registration (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities to be registered in such registration expenses therefor and forfeit their right to one (1) demand registration statement pursuant to Subsection 2.1(a); provided, further, that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Subsection 2.1(a). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.
- 2.7 <u>Delay of Registration</u>. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this <u>Section</u> 2.
 - 2.8 <u>Indemnification</u>. If any Registrable Securities are included in a registration statement under this <u>Section 2</u>:
- (a) To the extent permitted by law, the Company will indemnify and hold harmless (i) each selling Holder, and the partners, members, officers, directors and stockholders of each such Holder, (ii) legal counsel and accountants for each such Holder, (iii) any underwriter (as defined in the Securities Act) for each such Holder and (iv) each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such

expenses are incurred; <u>provided</u>, <u>however</u>, that the indemnity agreement contained in this <u>Subsection 2.8(a)</u> shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person or other aforementioned Person expressly for use in connection with such registration.

- (b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any) who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; provided, further, that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.
- (c) Promptly after receipt by an indemnified party under this <u>Subsection 2.8</u> of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this <u>Subsection 2.8</u>, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; <u>provided</u>, <u>however</u>, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one (1) separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time following the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this <u>Subsection 2.8</u>, to the extent that such failure materially prejudices the indemnifying party otherwise than under this <u>Subsection 2.8</u>.

- (d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions or other actions that resulted in such loss, claim, damage, liability or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (A) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (B) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; provided, further, that in no event shall a Holder's liability pursuant to this <u>Subsection 2.8(d)</u>, when combined with the amounts paid or payable by such Holder pursuant to <u>Subsection 2.8(b)</u>, exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.
- (e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.
- (f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this <u>Subsection</u> 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this <u>Section</u> 2, and otherwise shall survive the termination of this Agreement.
- 2.9 <u>Reports Under Exchange Act</u>. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:
- (a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

- (b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and
- (c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies) and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).
- 2.10 <u>Limitations on Subsequent Registration Rights</u>. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that would provide to such holder the right to include securities in any registration on other than either a pro rata basis with respect to the Registrable Securities or on a subordinate basis after all Holders have had the opportunity to include in the registration and offering all shares of Registrable Securities that they wish to so include; provided that this limitation shall not apply to any additional Investor who becomes a party to this Agreement in accordance with <u>Subsection 6.9</u>.
- 2.11 "Market Stand-off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter(s), during the period commencing on the date of the final prospectus relating to the registration by the Company for its own behalf of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1, and ending on the date specified by the Company and the managing underwriter(s) (such period not to exceed one hundred eighty (180) days), (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, or the transfer of any shares (A) by any Holder who is a natural person to any trust for the direct or indirect benefit of such Holder or such Holder, provided that, in each case, the trustee of such trust (in the case of clause (A)) or such natural persons (in the case of clause (B)) agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer

shall not involve a disposition for value, and shall be applicable to the Holders only if all officers, directors and stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock) are subject to the same restrictions. The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.11 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements. Notwithstanding the foregoing, in the event that the Company and/or the underwriter(s) in connection with the IPO agree to allow any officer, director or stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock) to hold its shares of Company capital stock subject to lock-up restrictions which are more favorable to such securityholder than the lock-up restrictions set forth in this Subsection 2.11, the lock-up restrictions applicable to the shares held by any Major Investor will be automatically amended to conform to the more favorable lock-up restrictions applicable to the shares held by such securityholder.

2.12 <u>Legend</u>. Each certificate, instrument or book entry representing (i) the Preferred Stock, (ii) the Registrable Securities and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

Notwithstanding the foregoing, the Company shall be obligated to reissue promptly unlegended certificates at the request of any Holder if the Company has completed its IPO or in connection with a sale of Registrable Securities by a Holder pursuant to SEC Rule 144 and the Holder shall have obtained an opinion of counsel (which counsel may be counsel to the Company) reasonably acceptable to the Company (it being understood that internal securities counsel of any Major Investor shall be deemed acceptable for transfers by any such Major Investor or Affiliate thereof) to the effect that the securities proposed to be disposed of may lawfully be so disposed of without registration, qualification and legend.

- 2.13 <u>Termination of Registration Rights</u>. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to <u>Subsection 2.1</u> or <u>Subsection 2.2</u> shall terminate upon earliest to occur of:
- (a) the closing of a Deemed Liquidation Event, as such term is defined in the Company's Third Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), in which the consideration received by the Investors is in the form of cash and/or freely-tradeable marketable securities;

- (b) such time as SEC Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three (3) month period without registration;
 - (c) the fifth (5th) anniversary of the IPO; and
- (d) the Redemption Date (as defined in the Certificate of Incorporation); <u>provided</u>, that if any Investor elects to exclude any shares of Preferred Stock held by such Investor from any redemption under Section (B)(6) of Article Fourth of the Certificate of Incorporation, then the right of such Investor to request registration or inclusion of Registrable Securities in any registration pursuant to <u>Subsection 2.1</u> or <u>Subsection 2.2</u> shall not terminate on the Redemption Date.
 - 3. Information and Observer Rights.
 - 3.1 Delivery of Financial Statements. The Company shall deliver:
- (a) to each Investor, as soon as practicable, but in any event within one hundred twenty (120) days after the end of each fiscal year of the Company, (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, (iii) a statement of stockholders' equity as of the end of such year, all such financial statements set forth in subsections (i) through (iii) audited and certified by independent public accountants of regionally recognized standing selected by the Company, and (iv) a comparison between (A) the actual amounts as of and for such fiscal year and (B) the comparable amounts included in the Budget (as defined below) for such year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such year;
- (b) to each Investor, as soon as practicable, but in any event within forty-five (45) days after the end of each fiscal quarter of the Company, (i) unaudited statements of income and cash flows for such fiscal quarter, (ii) an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements contemplated by subsection (i) or (ii) may (A) be subject to normal year-end audit adjustments and (B) not contain all notes thereto that may be required in accordance with GAAP), and (iii) a comparison between (x) the actual amounts as of and for such fiscal quarter and (y) the comparable amounts included in the Budget for such quarter, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such quarter;
- (c) to each Investor, as soon as practicable, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board and prepared on a quarterly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company;
 - (d) to each Major Investor, copies of all materials distributed to the Board; and

(e) to each Investor, promptly and accurately, and shall use its best efforts to cause its transfer agent to promptly respond to requests by such Investor from time to time for, information relating to, the (i) accounting or securities law matters required in connection with such Investor's audit or (ii) the actual holdings of such Investor, including in relation to the total outstanding number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the requesting Investor to calculate its respective percentage equity ownership in the Company.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this <u>Subsection 3.1</u> to the contrary, other than with respect to any Major Investor, the Company may cease providing the information set forth in this <u>Subsection 3.1</u> during the period starting with the date sixty (60) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; <u>provided</u> that the Company's covenants under this <u>Subsection 3.1</u> shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

- 3.2 <u>Visitation and Inspection</u>. The Company shall permit each Investor, at such Investor's expense, to visit and inspect the Company's properties, examine its books of account and records, and discuss the Company's affairs, finances and accounts with its officers, during normal business hours of the Company as may be reasonably requested by such Investor; <u>provided</u>, <u>however</u>, that the Company shall not be obligated pursuant to this <u>Subsection 3.2</u> to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.
- 3.3 Observer Rights. The Company shall invite one representative of each of (i) Fidelity, (ii) QSIP LP, on behalf of the Quantum/Aisling Investors and (iii) any other Investor for so long as such Investor (A) owns not less than nine percent (9%) of the shares of the then outstanding Preferred Stock (or an equivalent amount of Common Stock issued upon conversion thereof) and (B) is not entitled to appoint a member of the Board pursuant to Subsection 1.2 of that certain Second Amended and Restated Voting Agreement, dated as of the date hereof, by and among the Company and the other parties thereto (the "Voting Agreement"), to attend all meetings of the Board and any committee thereof in a nonvoting observer capacity and, in this respect, shall give each such representative copies of all notices, minutes, consents and other materials that it provides to its directors at the same time and in the same manner as provided to such directors; provided, however, that each such representative shall agree to hold in confidence

and trust all information so provided; <u>provided</u>, <u>further</u>, that the Company reserves the right to withhold any information and to exclude any such representative from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest.

- 3.4 <u>Termination of Information and Observer Rights</u>. The covenants set forth in <u>Subsection 3.1</u>, <u>Subsection 3.2</u> and <u>Subsection 3.3</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act or (iii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, in which the consideration received by the Investors is in the form of cash and/or freely-tradeable marketable securities, whichever event occurs first.
- 3.5 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection 3.5 by such Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company's confidential information or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that (1) each Investor that is a limited partnership or limited liability company may disclose such proprietary or confidential information to any former partners or members who retained an economic interest in such Investor, current or prospective partner of the partnership or any subsequent partnership under common investment management, limited partner, general partner, member or management company of such Investor (or any employee or representative of any of the foregoing); provided, that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information, (2) an Investor may disclose confidential information (i) to its attorneys, accountants, consultants and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company, (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Subsection 3.5, (iii) to any Affiliate, partner, member, stockholder or wholly owned subsidiary of such Investor in the ordinary course of business; provided, that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information or (iv) as may otherwise be required by law; provided, that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure and (3) each Investor that is a registered investment company within the meaning of the Investment Company Act, may make disclosures consistent with such Investor's required investment reporting practices. The obligations of an Investor under this Subsection 3.5 shall terminate two (2) years after the earlier of: (x) such time as the Investor no longer holds any shares of Preferred Stock and (y) a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation.

4. Rights to Future Stock Issuances.

- 4.1 Right of First Offer. Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Major Holder. A Major Holder shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates; provided, that, as a condition precedent to any issuance of such New Securities to such Affiliate, the Company shall require any such Affiliate (x) to become a party to this Agreement by executing a counterpart signature page hereto agreeing to be bound by and subject to the terms of this Agreement as a Major Holder and (y) to become a party to the Voting Agreement and that certain Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated as of the date hereof, by and among the Company and the other parties thereto by executing a counterpart signature page thereto agreeing to be bound by and subject to the terms of such agreements.
- (a) The Company shall give notice (the "**Offer Notice**") to each Major Holder, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.
- (b) By notification to the Company within twenty (20) days after the Offer Notice is given, each Major Holder may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Major Holder (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by such Major Holder) bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities) (such portion, a Major Holder's "**Pro Rata Amount**"). At the expiration of such twenty (20) day period, the Company shall promptly notify each Major Holder that elects to purchase or acquire all the shares available to it (each, a "**Fully Exercising Investor**") of any other Major Holder's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Major Holders were entitled to subscribe but that were not subscribed for by the Major Holders which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Preferred Stock and any other Derivative Securities then held, by such Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this <u>Subsection 4.1(b)</u> shall occur within the later of ninety (90) days following the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to <u>Subsection 4.1(c)</u>.
- (c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in <u>Subsection 4.1(b)</u>, then the Company may, during the ninety (90) day period following the expiration of the periods provided in <u>Subsection 4.1(b)</u>, offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less

than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days following the execution thereof, then the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Major Holders in accordance with this <u>Subsection 4.1</u>.

- (d) The right of first offer in this <u>Subsection 4.1</u> shall not be applicable to (i) Exempted Securities (as defined in the Certificate of Incorporation) or (ii) Common Stock issued in the IPO.
- (e) Notwithstanding any provision hereof to the contrary, in lieu of complying with the provisions of this <u>Subsection 4.1</u>, the Company may elect to give notice to the Major Holders within thirty (30) days after the issuance of any New Securities. Such notice shall describe the type, price and terms of the New Securities. Each Major Holder shall have twenty (20) days from the date notice is given to elect to purchase up to the number of New Securities that would, if purchased by such Major Holder, maintain such Major Holder's percentage-ownership position, calculated as set forth in <u>Subsection 4.1(b)</u> before giving effect to the issuance of such New Securities. The closing of such sale shall occur within sixty (60) days following the date that notice is given to the Major Holders.
- 4.2 <u>Termination</u>. The covenants set forth in <u>Subsection 4.1</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act or (iii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, in which the consideration received by the Investors is in the form of cash and/or freely-tradeable marketable securities, whichever event occurs first.

5. Additional Covenants.

- 5.1 <u>Insurance</u>. The Company has obtained, from financially sound and reputable insurers, Directors and Officers liability insurance in an amount and on terms and conditions satisfactory to the Board (including the directors appointed by Vivo, Valor and HBM (the "**Investor Directors**") pursuant to Subsection 1.2 of the Voting Agreement), and will use commercially reasonable efforts to cause such insurance policy to be maintained until such time as the Board (including the Investor Directors) determines that such insurance should be discontinued. Notwithstanding any other provision of this <u>Section 5.1</u> to the contrary, for so long as the Investor Directors are serving on the Board, the Company shall not cease to maintain a Directors and Officers liability insurance policy in an amount of at least five million dollars (\$5,000,000) unless approved by the Investor Directors.
- 5.2 <u>Employee Agreements</u>. The Company has caused or will cause (a) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement, and (b) any employee who receives shares or options to purchase shares of capital stock of the Company to enter into a one (1) year noncompetition and nonsolicitation agreement, substantially in the form approved by the Board. In addition, the Company shall not amend, modify, terminate, waive or otherwise alter to reduce the term of any noncompetition or nonsolicitation restriction in any such noncompetition and nonsolicitation agreement, without the consent of the Board.

- 5.3 <u>Board Matters</u>. Unless otherwise determined by the vote of a majority of the directors then in office, the Board shall meet at least quarterly in accordance with an agreed-upon schedule. The Company shall reimburse the directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board.
- 5.4 <u>Successor Indemnification</u>. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, the Certificate of Incorporation, or elsewhere, as the case may be.
- 5.5 Expenses of Counsel. In the event of a transaction which is a Sale of the Company (as defined in the Voting Agreement), the reasonable fees and disbursements, not to exceed \$200,000, of one (1) counsel for the Investors ("Investor Counsel"), in their capacities as stockholders, shall be borne and paid by the Company. At the outset of considering a transaction which, if consummated would constitute a Sale of the Company, the Company shall obtain the ability to share with the Investor Counsel (and such counsel's Investor clients) and shall share the confidential information (including, without limitation, the initial and all subsequent drafts of memoranda of understanding, letters of intent and other transaction documents and related noncompete, employment, consulting and other compensation agreements and plans) pertaining to and memorializing any of the transactions which, individually or when aggregated with others would constitute the Sale of the Company. The Company shall be obligated to share (and cause the Company's counsel and investment bankers to share) such materials when distributed to the Company's executives and/or any one or more of the other parties to such transaction(s). In the event that Investor Counsel deems it appropriate, in its reasonable discretion, to enter into a joint defense agreement or other arrangement to enhance the ability of the parties to protect their communications and other reviewed materials under the attorney client privilege, the Company shall, and shall direct its counsel to, execute and deliver to Investor Counsel and its clients such an agreement in form and substance reasonably acceptable to Investor Counsel. In the event that one or more of the other party or parties to such transactions require the Investor clients of Investor Counsel to enter into a confidentiality agreement and/or joint defense agreement in order to receive such information, then the Company shall share whatever information can be shared without entry into such agreement and shall, at the same time, in good faith work expeditiously to enable Investor Counsel and its clients to negotiate and enter into the appropriate agreement(s) without undue burden to the Investor clients of Investor Counsel.
- 5.6 <u>Indemnification Matters</u>. The Company hereby acknowledges that one (1) or more of the directors nominated to serve on the Board by the Investors (each a "**Fund Director**") may have certain rights to indemnification, advancement of expenses and/or insurance provided by one or more of the Investors and certain of their affiliates (collectively, the "**Fund Indemnitors**"). The Company hereby agrees (a) that it is the indemnitor of first resort (*i.e.*, its obligations to any such

Fund Director are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Fund Director are secondary), (b) that it shall be required to advance the full amount of expenses incurred by such Fund Director and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement by or on behalf of any such Fund Director to the extent legally permitted and as required by the Certificate of Incorporation or the Company's Bylaws (or any agreement between the Company and such Fund Director), without regard to any rights such Fund Director may have against the Fund Indemnitors, and (c) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of any such Fund Director with respect to any claim for which such Fund Director has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Fund Director against the Company.

- 5.7 Right to Conduct Activities. The Company hereby agrees and acknowledges that certain of the Investors, such Investors' respective affiliates and the Fidelity Investors are professional investment managers and/or funds (collectively, the "**Professional Investment Funds**"), and as such, invest in numerous portfolio companies, some of which may be deemed competitive with the Company's business (as currently conducted or as currently proposed to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, none of the Professional Investment Funds shall be liable to the Company for any claim arising out of, or based upon, (a) the investment by any of them in any entity competitive to the Company, or (b) actions taken by any partner, officer or other representative of any of them to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company; provided, however, that the foregoing shall not relieve (i) any of the Investors from liability associated with the unauthorized disclosure of the Company's confidential information obtained pursuant to this Agreement, or (ii) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.
- 5.8 <u>FCPA</u>. The Company represents that it shall not (and shall not permit any of its subsidiaries or affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA")), in each case, in violation of the FCPA, the U.K. Bribery Act or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) cease all of its or their respective activities, as well as remediate any actions taken by the Company, its subsidiaries or affiliates, or any of their respective directors, officers, managers, employees, independent contractors, representatives or agents in violation of the FCPA, the U.K. Bribery Act or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA, the U.K. Bribery Act or any other applicable anti-bribery or anti-corruption law. Upon request,

the Company agrees to provide responsive information and/or certifications concerning its compliance with applicable anti-corruption laws. The Company shall promptly notify each Investor if the Company becomes aware of any allegation, voluntary disclosure, investigation, prosecution or other enforcement action related to the FCPA or any other anti-corruption law. The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future, to comply in all material respects with all applicable laws.

- 5.9 <u>Approval of Material Transactions</u>. The Company shall not, without approval of the Board and, so long as at least 44,236,730 shares of Preferred Stock (which number is subject to appropriate adjustment for all stock splits, dividends, combinations, recapitalizations and the like) remain outstanding at such time, the holders of a majority of the shares of Preferred Stock, (a) consummate any material acquisition of any pharmaceutical product, or (b) enter into any line of business other than the acquisition, development, sale, distribution and lifecycle management of pharmaceutical products or biologics and any similar, related or complementary business or activity.
- 5.10 <u>Termination of Covenants</u>. The covenants set forth in this <u>Section 5</u> (other than <u>Subsection 5.4</u>) shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act or (iii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, in which the consideration received by the Investors is in the form of cash and/or freely-tradeable marketable securities, whichever event occurs first.

6. Miscellaneous.

- 6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by any party hereto to a transferee of the Preferred Stock or Common Stock, as the case may be, held by such party; provided, however, that (a) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Preferred Stock or Common Stock, as the case may be, with respect to which such rights are being transferred, and (b) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.
- 6.2 <u>Governing Law</u>. This Agreement shall be governed by the internal law of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware.

- 6.3 <u>Counterparts</u>. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
- 6.4 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.
- 6.5 Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) when sent by confirmed electronic mail or confirmed facsimile if sent during normal business hours of the recipient, if not, then on the next business day; (c) one (1) business day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt; or (d) five (5) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid. All communications to the Company shall be sent to:

Harmony Biosciences II, Inc.
[Address]
with a copy (which shall not constitute notice) to:
Katten Muchin Rosenman LLP
[Address]

All communications to the Investors and Key Holders shall be sent to each Investor's or Key Holder's address as set forth beneath its name on Schedule A or Schedule B hereto, as applicable, or at such other address as the relevant recipient may designate pursuant to the provisions of this Section 6.5, with a copy (which shall not constitute notice) to:

Cooley LLP [Address] DLA Piper LLP (US) [Address] Fenwick & West LLP
[Address]

Vedder Price LLP
[Address]

McDermott Will & Emery LLP
[Address]

Notwithstanding any of the foregoing, with respect to HBM, only a nationally recognized overnight courier shall be used to effectuate the delivery of any notices pursuant to this <u>Section</u> 6.5, and such notice or other communication for purposes of this Agreement shall not be treated as effective or having been given if some other delivery method is utilized.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of a majority of the Preferred Stock then outstanding; provided, that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (a) this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination or waiver applies to all Investors in the same fashion; provided, however, that in the event that the right of first offer in Section 4 is waived with respect to any issuance of New Securities, and one or more of the Major Holders that consented to such waiver (each a "Waiving Major Holder") nevertheless purchases any such New Securities, each Major Holder that is not a Waiving Major Holder shall be entitled to purchase their Pro Rata Amount in such offering (or such lesser amount as corresponding to the proportionate amount of New Securities purchased by such Waiving Major Holder, in the event such Waiving Major Holder purchased less than its Pro Rata Amount), (b) for so long as any Fidelity Investor holds any shares of Registrable Securities, the definition of "Affiliate" as it relates to a Fidelity Investor, the definitions of "Fidelity" and "Fidelity Investor", and Subsections 5.7, 6.14 and this clause (b) of this Subsection 6.6 may not be amended, terminated or waived without the prior written consent of Fidelity, (c) for so long as a Major Investor (other than any Fidelity Investor with respect to Subsections 2.11, 3.1, 3.2, 3.3, 3.4, 3.5 and this clause (c) of this Subsection 6.6, or any Quantum/Aisling Investor with respect to

Subsections 3.3, 3.4 and this clause (c) of this Subsection 6.6) holds any shares of Registrable Securities, any rights provided or granted to, or any obligations imposed upon, such Major Investor under <u>Subsections 2.11, 3.1, 3.2, 3.3, 3.4, 3.5</u> and this clause (c) of this <u>Subsection 6.6</u> may be amended or waived (either generally or in a particular instance) in a manner that adversely affects any such Major Investor only with the written consent of the Major Investors holding a majority of the shares of Preferred Stock held by all Major Investors (other than any Fidelity Investor with respect to Subsections 2.11, 3.1, 3.2, 3.3, 3.4, 3.5 and this clause (c) of this Subsection 6.6, or any Quantum/Aisling Investor with respect to Subsections 3.3, 3.4 and this clause (c) of this Subsection 6.6) adversely affected thereby, (d) for so long as any Fidelity Investor holds any shares of Registrable Securities, any rights provided or granted to, or any obligations imposed upon, such Fidelity Investor under Subsections 2.11, 3.1, 3.2, 3.3, 3.4, 3.5 and this clause (d) of this <u>Subsection 6.6</u> may be amended or waived (either generally or in a particular instance) in a manner that adversely affects such Fidelity Investor only with the written consent of such Fidelity Investor, (e) for so long as any Quantum/Aisling Investor holds any shares of Registrable Securities, any rights provided or granted to, or any obligations imposed upon, such Quantum/Aisling Investor under Subsections 3.3, 3.4 and this clause (e) of this Subsection 6.6 may be amended or waived (either generally or in a particular instance) in a manner that adversely affects such Quantum/Aisling Investor only with the written consent of such Quantum/Aisling Investor, (f) the definition of "Major Investor" may not be amended to delete any Major Investor without the consent of such Major Investor, (g) for so long as Novo holds any shares of Registrable Securities, the definition of "Affiliate" as it relates to Novo may not be amended, terminated or waived without the prior written consent of Novo and (h) this Agreement may not be amended, and no provision hereof may be waived, in each case, in any way that would adversely affect the rights of the Key Holders hereunder without the written consent of the holders of a majority of the Registrable Securities held by the Key Holders. The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination or waiver. Any amendment, termination or waiver effected in accordance with this <u>Subsection 6.6</u> shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition or provision. Notwithstanding the foregoing, this Agreement may not be terminated without the prior written consent of the holders of at least two thirds (66 2/3%) of the Preferred Stock then outstanding.

- 6.7 <u>Severability</u>. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal or unenforceable provision shall be reformed and construed so that it will be valid, legal and enforceable to the maximum extent permitted by law.
- 6.8 <u>Aggregation of Stock</u>. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.
- 6.9 <u>Additional Investors</u>. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of the Preferred Stock after the date hereof, whether

pursuant to the Purchase Agreement or otherwise, any purchaser of such shares of Preferred Stock may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement, and thereafter shall be deemed an "Investor" for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an "Investor" hereunder.

- 6.10 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties, including the Prior Agreement, is expressly canceled.
- 6.11 <u>Dispute Resolution</u>. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the Delaware Court of Chancery and any state appellate court therefrom within the State of Delaware, or if the Delaware Court of Chancery declines to accept jurisdiction over a particular action or proceeding, any federal court within the State of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the Delaware Court of Chancery and any state appellate court therefrom within the State of Delaware, or if the Delaware Court of Chancery declines to accept jurisdiction over a particular action or proceeding, any federal court within the State of Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OF THE COMPANY OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

The prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

- 6.12 <u>Delays or Omissions</u>. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.
- 6.13 <u>Acknowledgment</u>. The Company acknowledges that the Investors are in the business of venture capital investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict the Investors from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.
- 6.14 <u>Massachusetts Business Trust.</u> A copy of this Agreement and Declaration of Trust of each Investor affiliated with Fidelity, or any affiliate thereof, is on file with the Secretary of State of the Commonwealth of Massachusetts and notice is hereby given that this Agreement is executed on behalf of the trustees of such Investor or any affiliate thereof as trustees and not individually and that the obligations of this Agreement are not binding on any of the trustees, officers or stockholders of such Investor or any affiliate thereof individually but are binding only upon such Investor or any affiliate thereof and its assets and property.
- 6.15 <u>Investor Consent and Waiver</u>. Each of the holders of the Series A Preferred Stock and the Series B Preferred Stock executing this Agreement, and each of the Key Holders executing this Agreement, hereby:
- (a) approves and consents to the execution and filing of the Third Amended and Restated Certification of Incorporation and the terms thereof, including the creation of the Series C Preferred Stock and the increase in the number of authorized shares of Common Stock;
 - (b) approves and consents to the Series C Issuance; and
- (c) except to the extent set forth in the Purchase Agreement, elects not to purchase any Series C Preferred Stock in the Series C Issuance and irrevocably waives in the entirety, on behalf of itself and, together with all other holders of the Series A Preferred Stock and the Series B Preferred Stock executing this Agreement, on behalf of all Major Holders, their respective Series C ROFR and all notice requirements set forth in Section 4 of the Prior Agreement in connection therewith.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors' Rights Agreement as of the date first written above.

COMPANY:

HARMONY BIOSCIENCES II, INC.

By: /s/ Andrew Serafin

Name: Andrew Serafin Title: Assistant Secretary

SIGNATURE PAGE TO SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors' Rights Agreement as of the date first written above.

KEY HOLDER:

MARSHMAN FUND TRUST II

By: /s/ Charles Harris

Name: Charles Harris Title: Trustee

SIGNATURE PAGE TO SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

KEY HOLDER:

VALOR IV PHARMA HOLDINGS, LLC

By: /s/ Antonio J. Gracias

Name: Antonio J. Gracias

Title: Manager

INVESTOR:

PATRICK J. MORRIS REVOCABLE TRUST U/A/D 3/11/11

By: /s/ Patrick J. Harris

Name: Patrick J. Morris Title: Grantor and Trustee

INVESTOR:

 $HBM\ HEALTHCARE\ INVESTMENTS\ (CAYMAN)\ LTD.$

By: /s/ Jean Marc LeSieur

Name: Jean Marc LeSieur

Title: Director

INVESTOR:

WILBUR H. GANTZ III REVOCABLE TRUST

By: /s/ Wilbur H. Gantz, III

Name: Wilbur H. Gantz, III

Title: Trustee

INVESTOR:

BABAR GHIAS LIVING TRUST DATED AUGUST 7, 2017

By: /s/ Babar Ghias

Name: Babar Ghias Title: Grantor and Trustee

INVESTOR:

AISLING CAPITAL IV, LP

By: /s/ Robert Wenzel

Name: Robert Wenzel Title: CFO

INVESTOR:

TIMOTHY M. CUNNIFF REVOCABLE TRUST U/A/D 12/14/15

By: /s/ Timothy M. Cunniff

Name: Timothy M. Cunniff

Title: Trustee

INVESTOR:

MARSHMAN FUND TRUST II

By: /s/ Charles Harris

Name: Charles Harris Title: Trustee

	IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors	s' Rights Agreement as of the date first wri	tten
above			

INVESTOR:

/s/ Michael L. Derby

Michael L. Derby

INVESTOR:

/s/ Jeffrey B. Kindler

Jeffrey B. Kindler

INVESTOR:

VALOR IV PHARMA HOLDINGS, LLC

By: /s/ Antonio J. Gracias

Name: Antonio J. Gracias

Title: Manager

	IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors'	Rights Agreement as of the date first writter
above		

INVESTOR:

/s/ Darien Parhad

Darien Parhad

INVESTOR:

STAR INVESTMENT SERIES LLC - SERIES 46

By: /s/ James A. Star
Name: James A. Star

Name: James A. Star Title: Manager

INVESTOR:

PIVOTAL ALPHA LIMITED

By: /s/ Sun Xintong

Name: Sun Xintong Title: Director

INVESTOR:

PIVOTAL ALPHA LIMITED

By: /s/ Tang Chun Wai Nelson

Name: Tang Chun Wai Nelson Title: Director

Titie. Director

INVESTOR:

BIOPROJET PHARMA SAS

By: /s/ Jeanne-Marie Lecomte

Name: Jeanne-Marie Lecomte

Title: Chairman

	IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors'	' Rights Agreement as	s of the date first v	written
above				

T	N۱	C.	ΓC	۱D	

/s/ Robert Pelzer

Robert Pelzer

INVESTOR:

VIVO CAPITAL SURPLUS FUND VIII, L.P.

By: Vivo Capital VIII, LLC Its: General Partner

By: /s/ Albert Cha

Name: Albert Cha Title: Managing Member

INVESTOR:

VIVO CAPITAL SURPLUS FUND VIII, L.P.

By: Vivo Capital VIII, LLC Its: General Partner

By: /s/ Albert Cha

Name: Albert Cha Title: Managing Member

INVESTOR:

OCTAGON INVESTMENT PARTNERS, LLC

By: /s/ Michael E. Levy

Name: Michael E. Levy Title: Managing Partner

	IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors'	' Rights Agreement as	s of the date first v	written
above				

INVESTOR:

/s/ Spiro Katerinis

Spiro Katerinis

INVESTOR:

ANDREW T. SERAFIN REVOCABLE TRUST U/A/D FEBRUARY 9, 2011

By: <u>/s/ Andrew T. Serafin</u>

Name: Andrew T. Serafin

Title: Trustee

INVESTOR:

FIDELITY ADVISOR SERIES VII: FIDELITY ADVISOR HEALTH CARE FUND

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY CENTRAL INVESTMENT PORTFOLIOS LLC: FIDELITY HEALTH CARE CENTRAL FUND

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY GROWTH COMPANY COMMINGLED POOL

By: Fidelity Management & Trust Co.

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY MT. VERNON STREET TRUST: FIDELITY GROWTH COMPANY FUND

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY MT. VERNON STREET TRUST: FIDELITY SERIES GROWTH COMPANY FUND

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY SELECT PORTFOLIOS: HEALTH CARE PORTFOLIO

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

FIDELITY SELECT PORTFOLIOS PHARMACEUTICALS PORTFOLIO

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

VARIABLE INSURANCE PRODUCTS FUND IV: HEALTH CARE PORTFOLIO

By: /s/ Colm Hogan

Name: Colm Hogan Title: Authorized Signatory

INVESTOR:

NOVO HOLDINGS A/S

By: /s/ Martin Edwards

Name: Martin Edwards Title: Senior Partner

INVESTOR:

VENBIO GLOBAL STRATEGIC FUND II, L.P.

By: venBio Global Strategic GP II, L.P., its general partner

By: venBio Global Strategic GP II, Ltd., its general partner

By: /s/ Aaron Royston

Name: Aaron Royston Title: Vice President

INVESTOR:

SARA B. CROWN 65 TRUST

By: /s/ Debra Levin

Name: H. Debra Levin Title: Trustee

INVESTOR:

SCI PARTNERS LP

By: /s/ David Taylor
Name: David Taylor
Title: COO/GC

INVESTOR:

QSIP LP

By: Newlight Partners LP as Investment Manager

By: /s/ David Taylor

Name: David Taylor Title: Authorized Signatory

SCHEDULE A

INVESTORS

Name and Address

Marshman Fund Trust II [Address]

Valor IV Pharma Holdings, LLC

[Address]

Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund

[Address]

Fidelity Growth Company Commingled Pool

[Address]

Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund

[Address]

Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund

[Address]

Fidelity Select Portfolios: Health Care Portfolio

[Address]

Variable Insurance Products Fund IV: Health Care Portfolio

[Address]

Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund

[Address]

Fidelity Select Portfolios: Pharmaceuticals Portfolio

[Address]

Vivo Capital Fund VIII, L.P.

[Address]

Vivo Capital Surplus Fund VIII, L.P.

[Address]

HBM Healthcare Investments (Cayman) Ltd.

[Address]

Novo Holdings A/S [Address]

venBio Global Strategic Fund II, L.P. [Address]

Bioprojet Pharma, SAS [Address]

Pivotal Alpha Limited [Address]

Star Investment Series LLC – Series 46

[Address]

Sara B. Crown 65 Trust

[Address]

Octagon Investment Partners, LLC

[Address]

Patrick J. Morris Revocable Trust U/A/D 3/11/11

[Address]

Timothy M. Cunniff Revocable Trust U/A/D 12/14/15

[Address]

Babar Ghias Living Trust dated August 7, 2017

[Address]

Jeffrey B. Kindler

[Address]

Andrew T. Serafin Revocable Trust u/a/d February 9, 2011

[Address]

Spiro Katerinis [Address]

Darien Parhad

[Address]

Wilbur H. Gantz III Revocable Trust [Address]

Michael L. Derby [Address]

Robert Pelzer

[Address]

Aisling Capital IV, LP [Address]

QSIP LP

[Address]

SCI Partners LP [Address]

SCHEDULE B

KEY HOLDERS

Marshman Fund Trust II

[Address]

Valor IV Pharma Holdings, LLC [Address]