

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**AMENDMENT NO. 2 TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**HARMONY BIOSCIENCES HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
**630 W. Germantown Pike, Suite 215**  
**Plymouth Meeting, PA 19462**  
**Telephone: (484) 539-9800**

**82-2279923**  
(I.R.S. Employer  
Identification No.)

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

**John C. Jacobs**  
**President and Chief Executive Officer**  
**Harmony Biosciences Holdings, Inc.**  
**630 W. Germantown Pike, Suite 215**  
**Plymouth Meeting, PA 19462**  
**Telephone: (484) 539-9800**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

**Christopher D. Lueking, Esq.**  
**Latham & Watkins LLP**  
**330 North Wabash Avenue, Suite 2800**  
**Chicago, IL 60611**  
**Telephone: (312) 876-7700**

**Stephanie Wisdo**  
**General Counsel**  
**Harmony Biosciences Holdings, Inc.**  
**630 W. Germantown Pike, Suite 215**  
**Plymouth Meeting, PA 19462**  
**Telephone: (484) 539-9800**

**Robert Puopolo, Esq.**  
**Seo Salimi, Esq.**  
**Goodwin Procter LLP**  
**100 Northern Avenue**  
**Boston, MA 02210**  
**Telephone: (617) 570-1000**

**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 registered 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.

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.

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.

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  Accelerated filer  Non-accelerated filer  Smaller reporting company  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.

**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	\$123,023,251	\$15,968.42

- (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(a) of the Securities Act of 1933, as amended.
- (3) \$12,980 of this registration fee was previously paid by the Registrant in connection with the filing of its Registration Statement on Form S-1 on July 27, 2020.

**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.**

[Table of Contents](#)

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 August 11, 2020.**

**4,651,163 Shares**



**Common Stock**

---

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

We are offering 4,651,163 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 \$20.00 and \$23.00. We have applied to list our common stock on the Nasdaq Global Market 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 <sup>(1)</sup>	\$	\$
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 4,651,163 shares of our common stock, the underwriters have the option to purchase up to an additional 697,674 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**

**Piper Sandler**

---

Prospectus dated \_\_\_\_\_, 2020.

TABLE OF CONTENTS

	Page
<a href="#">BASIS OF PRESENTATION</a>	ii
<a href="#">TRADEMARKS</a>	ii
<a href="#">PROSPECTUS SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	15
<a href="#">CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	72
<a href="#">USE OF PROCEEDS</a>	74
<a href="#">CAPITALIZATION</a>	76
<a href="#">DIVIDEND POLICY</a>	78
<a href="#">DILUTION</a>	79
<a href="#">SELECTED CONSOLIDATED FINANCIAL DATA</a>	82
<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a>	84
<a href="#">BUSINESS</a>	109
<a href="#">MANAGEMENT</a>	155
<a href="#">EXECUTIVE COMPENSATION</a>	163
<a href="#">CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS</a>	179
<a href="#">PRINCIPAL STOCKHOLDERS</a>	185
<a href="#">DESCRIPTION OF CAPITAL STOCK</a>	189
<a href="#">SHARES ELIGIBLE FOR FUTURE SALE</a>	195
<a href="#">MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS</a>	198
<a href="#">UNDERWRITING</a>	202
<a href="#">LEGAL MATTERS</a>	209
<a href="#">EXPERTS</a>	209
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	209
<a href="#">INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</a>	F-1

---

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."

## **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 living with rare neurological disorders who have 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 H<sub>3</sub> receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of 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, following receipt of a Complete Response Letter, or CRL, for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020. 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 H<sub>3</sub> 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, which we plan on submitting in the second half of 2020. 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 symptoms. 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, 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. 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 H<sub>3</sub> receptor. It activates histaminergic neurons in the brain, a neuronal system involved in the maintenance of wakefulness, attention, vigilance and cognition. Pitolisant binds to H<sub>3</sub> 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 H<sub>1</sub> 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 H<sub>3</sub> 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

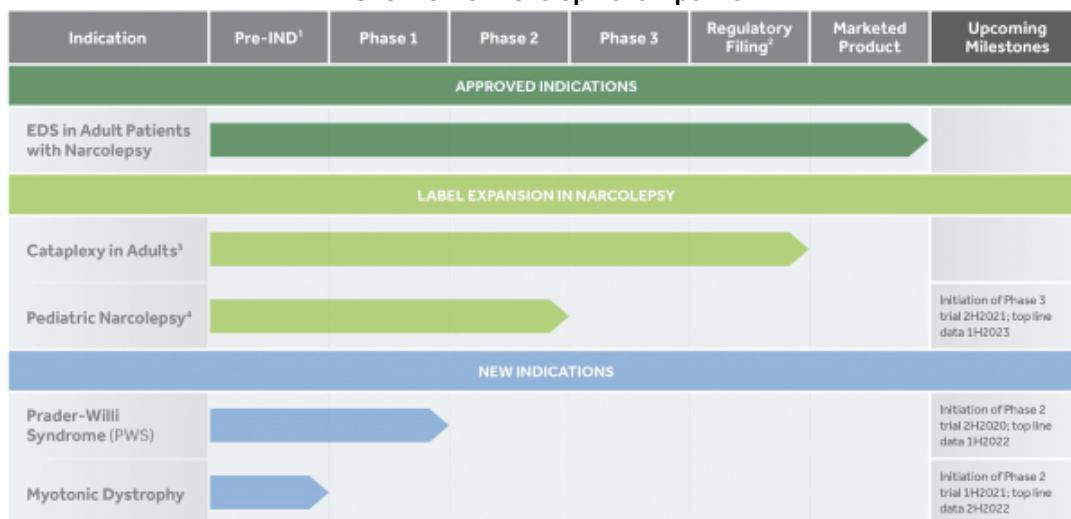
patients with narcolepsy and 14 of which were in other indications. These trials included a total of 1,513 unique patients, of whom 1,043 received pitolisant in double-blind, placebo-controlled studies, and others received pitolisant in single-blind or open-label trials. Three successful pivotal trials 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 H<sub>3</sub> receptor antagonist/inverse agonist approved by the FDA. It is approved 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 waking.** 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.

### Overview of Development Pipeline



1. 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 WAKIX. 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 CRL for the adult cataplexy indication in August 2019. Subsequently, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in our NDA in support of an adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission in the third quarter of 2020.  
 4. 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.

### 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 19 years of age or under. We believe that 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, following receipt of a CRL for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that were submitted in the NDA in support of the adult cataplexy indication. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. 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. We expect to submit the complete response resubmission during the third quarter of 2020, and depending on the timing and outcome of the FDA's subsequent review, we expect that the FDA could make a decision on the adult cataplexy indication as early as the second half of 2020. If the FDA requires us to conduct additional trials to gain a cataplexy indication in



adult patients with narcolepsy following our resubmission, we anticipate that any such clinical trials 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 in adult patients with narcolepsy 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 H<sub>3</sub> 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 for PWS 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. The primary symptom in patients with MD is myotonia, which is an impairment in the ability of muscles to relax, which results in progressive muscle weakness. 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. EDS and fatigue occur in approximately 80% to 90% of 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 H<sub>3</sub> 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. There are currently no FDA-approved treatments for patients with MD, representing a significant unmet medical need.

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. We anticipate commencing a Phase 2 clinical trial in adult patients with MD in the first half of 2021, subject to receiving authorization to proceed under an IND, which we plan on submitting in the second half of 2020. 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 living with rare neurological disorders who have 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, following receipt of a CRL for the adult cataplexy indication, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that were submitted in the NDA in support of the adult cataplexy indication. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication. We expect to submit this resubmission during the third quarter of 2020.
- **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 H<sub>3</sub> 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 June 30, 2020, over 1,750 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 2,700 unique patients (out of the approximately 42,000 diagnosed and treated narcolepsy patients in the United States). We have secured formulary access for over 166 million lives, which represents 70% 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, and for the three months ended June 30, 2020, net sales of WAKIX were \$38.0 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](http://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	4,651,163 shares.
Option to purchase additional shares	697,674 shares.
Common stock to be outstanding after this offering	62,980,540 shares (or 63,678,214 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	<p>We estimate, based upon an assumed initial public offering price of \$21.50 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 \$88.5 million (or \$102.5 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.</p> <p>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."</p>
Risk factors	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.
Dividend policy	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. Our board of directors has

elected to pay the cumulative accrued dividend in shares of common stock. We expect to issue an aggregate of 11,751,763 shares of common stock for cumulative accrued dividends to holders of our preferred stock in connection with this offering. 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 Global Market symbol

"HRMY"

The number of shares of common stock to be outstanding after this offering is based on 7,805,848 shares of our common stock outstanding as of June 30, 2020, plus an aggregate of 50,523,529 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 38,771,766 shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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:

- 2,462,071 shares of common stock issuable upon exercise of outstanding stock options and stock appreciation rights, or SARs, granted under the Harmony Biosciences Holdings, Inc. Amended and Restated Equity Incentive Plan, or the Equity Incentive Plan, as of June 30, 2020, at a weighted average exercise price of \$8.29 per share;
- 1,858,805 shares of common stock available for issuance under the Equity Incentive Plan as of June 30, 2020, which such shares will cease to be available for issuance at the time our 2020 Plan (as defined below) becomes effective;
- 2,612,925 shares of our common stock, based on an assumed public offering price of \$21.50 per share, which is the midpoint of the range set forth on the cover page of this prospectus, issuable upon the exercise of stock options, or the IPO Grants, granted under our 2020 Plan, which will become effective in connection with the completion of this offering with an exercise price equal to the initial public offering price;
- 6,927,859 shares of our common stock that will become available for future issuance under our new equity compensation plans, consisting of (1) 6,298,054 shares of our common stock under our 2020 Incentive Award Plan, or the 2020 Plan, which will become effective in connection with the completion of this offering (which number includes the IPO Grants and excludes any potential annual evergreen increases pursuant to the terms of the 2020 Plan); and (2) 629,805 shares of our common stock under our 2020 Employee Stock Purchase Plan, or the ESPP, which will become effective in connection with this offering (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP); and
- an aggregate of 410,239 shares of our common stock issuable upon the exercise of outstanding warrants held by OrbiMed Royalty Opportunities II, LP and OrbiMed Royalty & Credit Opportunities III, LP.

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 38,771,766 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 11,751,763 shares of our common stock;
- a one-for-8.215 reverse stock split of our common stock, effected on August 11, 2020;
- no exercise of the outstanding options described above after June 30, 2020;
- no exercise by the underwriters of their option to purchase up to 697,674 additional shares of common stock; and
- an initial public offering price of \$21.50 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 six months ended June 30, 2020 and 2019 and the summary consolidated balance sheet data as of June 30, 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 six-month period ended June 30, 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.

<b>Consolidated Statement of Operations Data:</b> <i>(U.S. dollars in thousands except share and per share data)</i>	<b>Six Months Ended June 30, 2020</b>	<b>Six Months Ended June 30, 2019</b>	<b>Year Ended December 31, 2019</b>	<b>Year Ended December 31, 2018</b>
Net product revenue	\$ 57,845	\$ —	\$ 5,995	\$ —
Cost of product sales	9,930	—	1,577	—
Gross profit	47,915	—	4,418	—
Operating expenses:				
Research and development	\$ 7,600	\$ 57,983	\$ 69,595	\$ 12,372
Sales and marketing	25,697	14,569	44,318	16,861
General and administrative	15,772	9,854	36,409	12,206
Total operating expenses	49,069	82,406	150,322	41,439
Operating loss	(1,154)	(82,406)	(145,904)	(41,439)
Loss on debt extinguishment	(22,639)	—	—	—
Other income (expense), net	(1,546)	—	—	—
Interest income (expense), net	(13,308)	(1,231)	(6,073)	1,541
Loss before taxes	(38,647)	(83,637)	(151,977)	(39,898)
Income taxes	—	—	—	—
Net loss and comprehensive loss	<u>\$ (38,647)</u>	<u>\$ (83,637)</u>	<u>\$ (151,977)</u>	<u>\$ (39,898)</u>
Accumulation of yield on preferred stock	(20,891)	(16,629)	(35,231)	(30,185)
Net loss available to common stockholders	<u>\$ (59,538)</u>	<u>\$ (100,266)</u>	<u>\$ (187,208)</u>	<u>\$ (70,083)</u>
Loss per share:				
Loss per share, basic and diluted <sup>(1)(2)</sup>	<u>\$ (7.63)</u>	<u>\$ (12.89)</u>	<u>\$ (24.07)</u>	<u>\$ (7.91)</u>
Weighted average number of shares of common stock, basic and diluted	<u>7,798,928</u>	<u>7,777,100</u>	<u>7,777,441</u>	<u>8,857,622</u>
Pro Forma net loss per share, basic and diluted (unaudited) <sup>(1)(2)</sup>	<u>\$ (0.70)</u>		<u>\$ (3.09)</u>	
Pro Forma weighted average shares of common stock outstanding, basic and diluted (unaudited)	55,278,574		49,239,211	

- (1) See Note 13 to our financial statements for the six months ended June 30, 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.

<b>Consolidated Balance Sheet Data:</b> <i>(U.S. dollars in thousands except share and per share data)</i>	<b>As of June 30, 2020</b>		
	<b>Actual</b>	<b>Pro Forma<sup>(2)</sup></b>	<b>Pro Forma As Adjusted<sup>(3)</sup></b>
Cash and cash equivalents	\$ 76,280	76,280	164,792
Working capital <sup>(1)</sup>	77,226	77,226	165,738
<b>Total assets</b>	<b>168,819</b>	<b>168,819</b>	<b>257,331</b>
Warrant liability	3,943	3,943	3,943
Long-term debt, net	192,518	192,518	192,518
Convertible preferred stock	434,011	—	—
<b>Total stockholders' (deficit) equity</b>	<b>(483,362)</b>	<b>(49,351)</b>	<b>39,161</b>

- (1) We define working capital as current assets less current liabilities.
- (2) 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 38,771,766 shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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 4,651,163 shares of our common stock in this offering at an assumed initial public offering price of \$21.50 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 \$21.50 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 \$4.3 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 \$20.0 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 \$83.6 million for the six months ended June 30, 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 June 30, 2020, we had an accumulated deficit of \$483.4 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 \$57.8 million and zero for the six months ended June 30, 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 June 30, 2020, we had an accumulated deficit of \$483.4 million, and available cash and cash equivalents of \$76.3 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 June 30, 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;

## Table of Contents

- 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

## [Table of Contents](#)

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 June 30, 2020, we had an accumulated deficit of \$483.4 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;

## Table of Contents

- 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 post-marketing 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;



## Table of Contents

- 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

## [Table of Contents](#)

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 have had 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. In particular, we expect that our ability to convert patients to revenue and the corresponding revenue growth rate in the third and fourth quarters of 2020 and possible future quarters will be adversely impacted by the ongoing COVID-19 pandemic. We have seen impacts in our ability to access HCPs, and fewer patient visits to their HCPs, resulting in fewer prescriptions being written. Additionally, the significant rise in unemployment and loss of insurance coverage has resulted in some current WAKIX patients and new WAKIX patients being unable to pay for their prescriptions and, for those who meet eligibility requirements, moving to patient assistance programs.

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;

## [Table of Contents](#)

- 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

## [Table of Contents](#)

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

## [Table of Contents](#)

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;

## Table of Contents

- 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.



## [Table of Contents](#)

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 June 30, 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.

## [Table of Contents](#)

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

## [Table of Contents](#)

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 in adults, for which we intend to 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, and therefore the FDA did not approve WAKIX for this indication during the initial NDA review. Subsequently, in June 2020, we received a general advice letter from the FDA stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in the NDA in support of the adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020. 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.

## [Table of Contents](#)

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

## [Table of Contents](#)

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

## [Table of Contents](#)

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;

## [Table of Contents](#)

- 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

## [Table of Contents](#)

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

## [Table of Contents](#)

- 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 or condition in order to receive orphan drug exclusivity. 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;

## [Table of Contents](#)

- 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



## [Table of Contents](#)

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;

## [Table of Contents](#)

- 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.

## [Table of Contents](#)

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 ever-increasing 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 filing 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

## [Table of Contents](#)

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

## [Table of Contents](#)

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 \$(2.02) per share of our common stock as of June 30, 2020. Based on the assumed initial public offering price of \$21.50 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 \$21.97 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 Global Market, 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;

## [Table of Contents](#)

- 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 July 31, 2020, our directors, officers, five percent or greater stockholders, and their respective affiliates beneficially owned in the aggregate approximately 92.8% of our outstanding voting stock and, upon the completion of this offering, that same group will beneficially own in the aggregate approximately 86.0% 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 7,805,848 shares of common stock outstanding as of July 31, 2020, the conversion of all of our preferred stock immediately prior to the closing of this offering into 38,771,766 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 11,751,763 shares of our common stock, upon the closing of this offering, we will have 62,980,540 shares of common stock outstanding.

## [Table of Contents](#)

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 58,273,144 shares of common stock, or 99.9%, based on shares outstanding on an as-converted basis as of July 31, 2020, the conversion of all of our preferred stock immediately prior to the closing of this offering into 38,771,766 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 11,751,763 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.

***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;



## [Table of Contents](#)

- 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;

## [Table of Contents](#)

- 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.

## [Table of Contents](#)

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 \$21.50 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 \$88.5 million (or \$102.5 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 \$78.0 million to fund external clinical development for 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 \$21.50 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 \$4.3 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.

---

[Table of Contents](#)

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 \$20.0 million, assuming that the price per share for the offering remains at \$21.50 (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 June 30, 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 38,771,766 shares of our common stock; (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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 4,651,163 shares of common stock in this offering at an assumed initial public offering price of \$21.50 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 June 30, 2020		
	Actual	Pro forma	Pro Forma As adjusted
	(in thousands, except share data)		
Cash and cash equivalents	\$ 76,280	76,280	164,792
Long-term debt, net	192,518	192,518	192,518
Convertible preferred stock warranty liability	3,943	3,943	3,943
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	434,011	—	—
Preferred stock, par value \$0.00001 per share; no shares authorized, issued and outstanding, actual; 10,000,000 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, 7,805,848 shares issued and outstanding, actual; 500,000,000 shares authorized, 57,652,956 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 62,980,540 shares issued and outstanding, pro forma as adjusted	—	1	1
Additional paid-in capital	—	434,011	522,523
Accumulated deficit	(483,362)	(483,363)	(483,363)
<b>Total stockholders' (deficit) equity</b>	<u>(483,362)</u>	<u>(49,351)</u>	<u>39,161</u>
<b>Total capitalization</b>	<u>147,110</u>	<u>147,110</u>	<u>235,622</u>



## [Table of Contents](#)

Each \$1.00 increase or decrease in the assumed initial public offering price of \$21.50 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 \$4.3 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 \$20.0 million, assuming that the price per share for the offering remains at \$21.50 (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:

- 2,462,071 shares of common stock issuable upon exercise of outstanding stock options and SARS granted under our Equity Incentive Plan as of June 30, 2020, at a weighted average exercise price of \$8.29 per share;
- 1,858,805 shares of common stock available for issuance under our Equity Incentive Plan as of June 30, 2020, which such shares will cease to be available for issuance at the time our 2020 Plan becomes effective;
- 2,612,925 shares of our common stock, based on an assumed public offering price of \$21.50 per share, which is the midpoint of the range set forth on the cover page of this prospectus, issuable upon the exercise of stock options, shares of our common stock issuable in connection with the IPO Grants granted under our 2020 Plan, which will become effective in connection with the completion of this offering with an exercise price equal to the initial public offering price;
- 6,927,859 shares of our common stock available for future issuance under our new equity compensation plans, consisting of (1) 6,298,054 shares of our common stock under the 2020 Plan, which will become effective in connection with the completion of this offering (which number includes the IPO Grants and excludes any potential annual evergreen increases pursuant to the terms of the 2020 Plan); and (2) 629,805 shares of our common stock under the ESPP, which will become effective in connection with this offering (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP); and
- an aggregate of 410,239 shares of our common stock issuable upon the exercise of outstanding warrants held by OrbiMed Royalty Opportunities II, LP and OrbiMed Royalty & Credit Opportunities III, LP.

## 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. Our board of directors has elected to 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 in shares of common stock equal to 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. We expect to issue an aggregate of 11,751,763 shares of common stock, consisting of (i) 11,143,551 shares of our common stock for cumulative accrued dividends to holders of our Series A preferred stock, (ii) 277,860 shares of our common stock for cumulative accrued dividends to holders of our Series B preferred stock and (iii) 330,352 shares of our common stock to holders of our Series C preferred stock. Stock dividends will not be paid on any shares of our 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 June 30, 2020 was \$(551.9) million, or \$(70.70) 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 7,805,848 shares of our common stock outstanding as of June 30, 2020.

Our pro forma net tangible book value (deficit) as of June 30, 2020 was \$(117.8) million, or \$(2.02) 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 38,771,766 shares of common stock and (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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 4,651,163 shares of our common stock in this offering at an assumed initial public offering price of \$21.50 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 June 30, 2020, would have been \$(29.3) million, or \$(0.47) per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$1.55 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$21.97 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	\$21.50
Historical net tangible book value (deficit) per share as of June 30, 2020	\$(70.70)
Increase per share attributable to the conversion of outstanding preferred stock and payment of accrued dividend	68.68
Pro forma net tangible book value per share as of June 30, 2020 before this offering	(2.02)
Increase in pro forma as adjusted net tangible book value per share attributable to investors in this offering	1.55
Pro forma as adjusted net tangible book value per share after this offering	(0.47)
Dilution per share to new common stock investors in this offering	\$21.97

A \$1.00 increase (decrease) in the assumed initial public offering price of \$21.50 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 \$0.07, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately \$0.93, 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.

## [Table of Contents](#)

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 \$(0.23) per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$1.80 per share and the dilution in pro forma as adjusted net tangible book value to new investors would be \$21.73 per share, in each case assuming an initial public offering price of \$21.50 per share, which is the midpoint of the price range listed on the cover page of this prospectus.

The following table summarizes, as of June 30, 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 \$21.50 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 Consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders	58,329,377	93%	\$ 345,375,182	78%	\$ 5.92
New investors	4,651,163	7%	100,000,000	22%	21.50
<b>Total</b>	<b>62,980,540</b>	<b>100%</b>	<b>\$445,375,182</b>	<b>100%</b>	<b>\$ 7.07</b>

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$21.50 per share would increase (decrease) the total consideration paid by new investors and the total consideration paid by all stockholders by \$4.3 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:

- 2,462,071 shares of common stock issuable upon exercise of outstanding stock options and SARs granted under our Equity Incentive Plan as of June 30, 2020, at a weighted average exercise price of \$8.29 per share;
- 1,858,805 shares of common stock available for issuance under our Equity Incentive Plan as of June 30, 2020, which such shares will cease to be available for issuance at the time our 2020 Plan becomes effective;
- 2,612,925 shares of our common stock, based on an assumed public offering price of \$21.50 per share, which is the midpoint of the range set forth on the cover page of this prospectus, issuable upon the exercise of stock options, issuable in connection with the IPO Grants granted under our 2020 Plan, which will become effective in connection with the completion of this offering with an exercise price that is equal to the initial public offering price;
- 6,927,859 shares of our common stock available for future issuance under our new equity compensation plans, consisting of (1) 6,298,054 shares of our common stock under the 2020 Plan, which will become effective in connection with the completion of this offering (which number includes the IPO Grants and excludes any potential annual evergreen increases pursuant to the terms of the 2020 Plan); and (2) 629,805 shares of our common stock under the ESPP, which will become effective in connection with this offering (which number does not include any potential annual evergreen increases pursuant to the terms of the ESPP); and
- an aggregate of 410,239 shares of our common stock issuable upon the exercise of outstanding warrants held by OrbiMed Royalty Opportunities II, LP and OrbiMed Royalty & Credit Opportunities III, LP.

---

[Table of Contents](#)

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 June 30, 2020, the pro forma as adjusted net tangible book value per share after this offering would be \$(0.45), and total dilution per share to new investors would be \$21.95.

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 92% 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 5,348,837, or approximately 8% of the total number of shares of our 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 six months ended June 30, 2020 and 2019 and the selected consolidated balance sheet data as of June 30, 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 six-month period ended June 30, 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.

## Table of Contents

<b>Consolidated Statement of Operations Data:</b> <i>(U.S. dollars in thousands except share and per share data)</i>	<b>Six Months Ended June 30, 2020</b>	<b>Six Months Ended June 30, 2019</b>	<b>Year Ended December 31, 2019</b>	<b>Year Ended December 31, 2018</b>
Net product revenue	\$ 57,845	\$ —	\$ 5,995	\$ —
Cost of product sales	9,930	—	1,577	—
Gross profit	47,915	—	4,418	—
Operating expenses:				
Research and development	\$ 7,600	\$ 57,983	\$ 69,595	\$ 12,372
Sales and marketing	25,697	14,569	44,318	16,861
General and administrative	15,772	9,854	36,409	12,206
Total operating expenses	49,069	82,406	150,322	41,439
Operating loss	(1,154)	(82,406)	(145,904)	(41,439)
Loss on debt extinguishment	(22,639)	—	—	—
Other income (expense), net	(1,546)	—	—	—
Interest income (expense), net	(13,308)	(1,231)	(6,073)	1,541
Loss before taxes	(38,647)	(83,637)	(151,977)	(39,898)
Income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (38,647)	\$ (83,637)	\$ (151,977)	\$ (39,898)
Accumulation of yield on preferred stock	(20,891)	(16,629)	(35,231)	(30,185)
Net loss available to common stockholders	\$ (59,538)	\$ (100,266)	\$ (187,208)	\$ (70,083)
Loss per share:				
Loss per share, basic and diluted <sup>(1)(2)</sup>	\$ (7.63)	\$ (12.89)	\$ (24.07)	\$ (7.91)
Weighted average number of common stock, basic and diluted	7,798,928	7,777,100	7,777,441	8,857,622
Pro Forma net loss per share, basic and diluted (unaudited) <sup>(1)(2)</sup>	\$ (0.70)		\$ (3.09)	
Pro Forma weighted average shares of common stock outstanding, basic and diluted (unaudited)	55,278,574		49,239,211	

- (1) See Note 13 to our financial statements for the six months ended June 30, 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.

<b>Consolidated Balance Sheet Data:</b> <i>(U.S. dollars in thousands except share and per share data)</i>	<b>June 30, 2020</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Cash and cash equivalents	\$ 76,280	\$ 24,457	\$ 83,523
Working capital <sup>(1)</sup>	77,226	11,605	79,453
Total assets	\$ 168,819	\$ 106,703	\$ 89,282
Warrant liability	3,943	—	—
Long-term debt, net	192,518	97,946	—
Convertible preferred stock	434,011	411,277	324,201
Total stockholders' (deficit) equity	(483,362)	(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 living with rare neurological disorders who have 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 H<sub>3</sub> receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of 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, following receipt of a Complete Response Letter for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020. 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 H<sub>3</sub> 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, which we plan on submitting in the second half of 2020. 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.



## [Table of Contents](#)

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 June 30, 2020, there was \$200.0 million outstanding under the Credit Agreement.

In the six months ended June 30, 2020, we generated \$57.8 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 six months ended June 30, 2020 and 2019, we incurred net losses of \$38.6 million and \$83.6 million, respectively. We had an accumulated deficit as of June 30, 2020 of \$483.4 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 June 30, 2020, our cash, cash equivalents and restricted cash were \$77.0 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 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;

## [Table of Contents](#)

- 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. Furthermore, if we are granted approval for a cataplexy indication in adult patients with narcolepsy, we would be required to pay the resulting \$102.0 million milestone payment to Bioprojet. 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 pandemic on our employees, patients and our business. We experienced limited financial impacts during the first two quarters 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 particular, we expect that our

## [Table of Contents](#)

ability to convert patients to revenue and the corresponding revenue growth rate in the third and fourth quarters of 2020 and possible future quarters will be adversely impacted by the ongoing COVID-19 pandemic. We have seen impacts in our ability to access HCPs, and fewer patient visits to their HCPs, resulting in fewer prescriptions being written. Additionally, the significant rise in unemployment and loss of insurance coverage has resulted in some current WAKIX patients and new WAKIX patients being unable to pay for their prescriptions and, for those who meet eligibility requirements, moving to patient assistance programs.

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 June 30, 2020, we executed over 750 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 500 HCP targets through June 30, 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 have begun to allow limited in-person interactions pursuant to health authority and local government guidelines, our field teams have started to re-initiate in-person interactions with healthcare professionals and customers, but the timing and level of engagement 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.

## [Table of Contents](#)

### *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 site visits and 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-at-home” 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 six months ended June 30, 2020, we had \$57.8 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 six months ended June 30, 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 \$3.7 million and \$0 in the six months ended June 30, 2020 and June 30, 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 June 30, 2020 we expect our existing inventory to have minimal obsolescence. We will continue to assess 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. We also have research and development expenses related to our team of Medical Science Liaisons, or MSLs, who interact with key opinion leaders, with a focus on the science, the role of histamine in sleep-wake state stability and the novel mechanism of action of pitolisant. In

## [Table of Contents](#)

addition, the MSLs support our market access team with clinical data presentations to payors upon request. 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 advance our clinical programs in patients with PWS, MD and pediatric narcolepsy, and continue to expand our product-candidate pipeline. We may also have to conduct another clinical trial to gain an adult cataplexy indication. 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 development programs and any further clinical trials related to 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;

## [Table of Contents](#)

- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- 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,

## [Table of Contents](#)

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 \$2.6 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. Since entering into the right of use agreement in November 2019 through June 30, 2020, we paid fees of \$0.6 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.

### *Other Income / Expense, Net*

Other income / expense, net consists primarily of costs of the fair value of the warrants associated with the OrbiMed Credit Agreement.

### *Interest Income / Interest Expense*

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



## Consolidated Statements of Operations

### Comparison of the Six Months Ended June 30, 2020 and 2019

The following table sets forth our results of operations for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	Change	
			Amount	%
			<i>(dollars in thousands)</i>	
Net product revenue	\$ 57,845	\$ —	\$ 57,845	n/a
Cost of product sales	9,930	—	9,930	n/a
Gross profit	47,915	—	47,915	n/a
Operating expenses:				
Research and development	\$ 7,600	\$ 57,983	\$(50,383)	(86.9)%
Sales and marketing	25,697	14,569	11,128	76.4%
General and administrative	15,772	9,854	5,918	60.0%
Total operating expenses	49,069	82,406	(33,337)	(40.4)%
Operating loss	(1,154)	(82,406)	81,252	(98.6)%
Loss on debt extinguishment	(22,639)	—	(22,639)	n/a
Other income (expense), net	(1,546)	—	(1,546)	n/a
Interest income (expense), net	(13,308)	(1,231)	(12,077)	(981.1)%
Loss before provision for income taxes	(38,647)	(83,637)	44,990	(53.8)%
Provision for income taxes	—	—	—	n/a
Net loss	\$(38,647)	\$(83,637)	\$ 44,990	(53.8)%

#### Net Product Revenue

Net product revenue increased to \$57.8 million for the six months ended June 30, 2020 compared to no sales in the same period in 2019 due to the commercial launch of WAKIX on November 1, 2019. Net product revenue was \$38.0 million for the three months ended June 30, 2020 representing an increase of \$18.2 million from \$19.8 million for the three months ended March 31, 2020, driven by increased adoption of WAKIX following commercial launch.

#### Cost of Product Sales

Cost of product sales increased to \$9.9 million for the six months ended June 30, 2020 compared to no costs in the same period in 2019 due to the commercial launch of WAKIX on November 1, 2019. Cost of product sales were \$6.5 million for the three months ended June 30, 2020 representing an increase of \$3.0 million from \$3.5 million for the three months ended March 31, 2020, driven by increased adoption of WAKIX following commercial launch.

#### Research and Development Expenses

Research and development expenses decreased to \$7.6 million for the six months ended June 30, 2020 compared to \$58.0 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. Research and development expense was \$4.2 million for the three months ended June 30, 2020 representing an increase of \$0.8 million from \$3.4 million for the three months ended March 31, 2020, driven by an increase in clinical activity.

### ***Sales and Marketing Expenses***

Sales and marketing expenses were \$25.7 million for the six months ended June 30, 2020 compared to \$14.6 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. Sales and marketing expenses were \$12.4 million for the three months ended June 30, 2020 representing a decrease of \$0.9 million from \$13.3 million for the three months ended March 31, 2020, driven by a decrease in travel related expenses of our field force and a decrease in bonus payments to our field force.

### ***General and Administrative Expenses***

General and administrative expenses were \$15.8 million for the six months ended June 30, 2020, compared to \$9.9 million for the same period in 2019 due primarily to intangible asset amortization and additional fees associated with this offering. General and administrative expenses was \$7.6 million for the three months ended June 30, 2020, representing a decrease of \$0.6 million from \$8.2 million for the three months ended March 31, 2020, driven by decreased costs associated with this offering.

### ***Loss on Debt Extinguishment***

Loss on debt extinguishment was \$22.6 million for the six months ended June 30, 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.

### ***Other Income (Expense), Net***

Other income (expense), net was \$1.5 million for the six months ended June 30, 2020, compared to zero for the same period in 2019, due to the change in the fair value of warrants. Other expense was \$0.4 million for the three months ended June 30, 2020, representing a decrease of \$0.7 million from \$1.1 million for the three months ended March 31, 2020, driven by the change in the fair value of the warrants.

### ***Interest Income (Expense), Net***

Interest expense was \$13.3 million for the six months ended June 30, 2020, compared to \$1.2 million for the same period ended 2019. Interest expense, net, for the six months ended June 30, 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. Interest expense was \$6.9 million for the three months ended June 30, 2020, representing an increase of \$0.5 million from \$6.4 million during the three months ended March 31, 2020, driven by interest on outstanding debt facility, amortization of debt issuance 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 six months ended June 30, 2020 and 2019 was 0.0% and 0.0%, respectively. Currently, we have recorded a full valuation allowance against our 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	Year Ended December 31, 2018	Change	
			Amount	%
	<i>(dollars in thousands)</i>			
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%
Operating loss	(145,904)	(41,439)	104,465	252.1%
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 June 30, 2020, we have received aggregate proceeds of \$345.0 million from sales of our convertible preferred stock. As of June 30, 2020, we had cash, cash equivalents and restricted cash of \$77.0 million and accumulated deficit of \$483.4 million. As of June 30, 2020, we had outstanding debt, net of issuance costs, of \$192.5 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. Borrowings under the Credit Agreement are collateralized by all of the Company's assets, excluding the intellectual property licensed through the Bioprojet License 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.

## [Table of Contents](#)

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 six months ended June 30, 2020 and 2019 and the years ended December 31, 2019 and 2018:

<i>(U.S. dollars in thousands)</i>	Six months Ended June 30, 2020	Six months Ended June 30, 2019	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash used in operating activities	\$(21,870)	\$(27,996)	\$ (75,436)	\$ (38,799)
Net cash used in investing activities	(2)	(50,083)	(127,149)	(1,342)
Net cash provided by financing activities	73,695	70,691	143,769	21,615
Net increase/(decrease) in cash, cash equivalents and restricted cash	<u>51,823</u>	<u>\$ (7,388)</u>	<u>\$ (58,816)</u>	<u>\$ (18,526)</u>

### **Operating Activities**

Net cash used in operating activities decreased to \$21.9 million for the six months ended June 30, 2020 compared to \$28.0 million the same period in 2019. This decrease was primarily attributable to company growth associated with the commercial launch of WAKIX.

Net cash used in operating activities for the six months ended June 30, 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 \$5.3 million related to intangible amortization and fair value of warrants. Net working capital excluding cash decreased by \$12.9 million due to company growth and the commercial launch of WAKIX.

Net cash used in operating activities for the six months ended June 30, 2019 consisted of net loss of \$83.6 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.

## [Table of Contents](#)

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***

Net cash used in investing activities for the six months ended June 30, 2020 was nominal compared to \$50.1 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 six months ended June 30, 2020 was \$73.7 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 six months ended June 30, 2019 was \$70.7 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,

## [Table of Contents](#)

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 continued negative impact of the COVID-19 pandemic on our business, including sales of WAKIX;
- 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; and
- the costs of operating as a public company.

### **Contractual Obligations and Commitments**

As of June 30, 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 June 30, 2020.

## [Table of Contents](#)

	Payments Due by Period				
	Total	Less Than One Year	1–3 Years <i>(in thousands)</i>	3–5 Years	More Than Five Years
Operating lease obligations	\$1,953	\$ 586	\$ 1,366	\$ —	\$ —

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 June 30, 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 of June 30, 2020, we have an accumulated deficit of \$483.4 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 six months ended June 30, 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 fulfillment 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.

## [Table of Contents](#)

### *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.

## [Table of Contents](#)

*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 range of assumptions used to estimate the fair value of awards.

	2020	2019	2018
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	83.90 - 95.80%	95.30 - 99.30%	112.00%
Risk-free interest rate	0.49 - 0.51%	1.60 - 2.59%	2.39%
Lack of marketability discount	17.37 - 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,

## [Table of Contents](#)

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 through December 31, 2019, we used a combination of both, Backsolve and DCF, to estimate the fair value of our common stock. For our valuations performed as of March 31, 2020 and June 30, 2020, we used a DCF to estimate the fair value of our common stock. Furthermore, as of each of the valuation dates and even being an early stage commercial 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 June 30, 2020, March 31, 2020, December 31, 2019, August 14, 2019, February 13, 2019, and December 31, 2018 were \$16.02, \$13.72, \$7.15, \$6.66, \$5.34 and \$4.27, respectively, per share. All option grants prior to March 31, 2020 were made above such valuations at an exercise price of \$8.22 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.

[Table of Contents](#)**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 on each grant date:

<b>Grant Date</b>	<b>Number of Shares Subject to Options Granted</b>	<b>Per Share Exercise Price of Options</b>	<b>Fair Value per Share on Grant Date</b>	<b>Per Share Estimated Fair Value of Options on Grant Date</b>
January 7, 2019	40,166	\$ 8.22	\$ 4.28	\$ 3.29
January 28, 2019	12,172	\$ 8.22	\$ 4.28	\$ 3.29
February 11, 2019	2,434	\$ 8.22	\$ 4.28	\$ 3.29
March 11, 2019	6,086	\$ 8.22	\$ 5.34	\$ 4.11
March 25, 2019	8,520	\$ 8.22	\$ 5.34	\$ 4.11
April 8, 2019	4,869	\$ 8.22	\$ 5.34	\$ 4.11
April 15, 2019	37,734	\$ 8.22	\$ 5.34	\$ 4.11
April 22, 2019	29,822	\$ 8.22	\$ 5.34	\$ 4.11
April 29, 2019	21,909	\$ 8.22	\$ 5.34	\$ 4.11
May 13, 2019	4,869	\$ 8.22	\$ 5.34	\$ 4.11
May 20, 2019	13,389	\$ 8.22	\$ 5.34	\$ 4.11
June 17, 2019	120,483	\$ 8.22	\$ 5.34	\$ 4.11
June 24, 2019	4,868	\$ 8.22	\$ 5.34	\$ 4.11
July 1, 2019	52,332	\$ 8.22	\$ 5.34	\$ 4.11
August 5, 2019	8,520	\$ 8.22	\$ 5.34	\$ 4.11
August 26, 2019	608	\$ 8.22	\$ 6.66	\$ 5.10
September 30, 2019	3,651	\$ 8.22	\$ 6.66	\$ 5.10
October 21, 2019	3,651	\$ 8.22	\$ 6.66	\$ 5.10
October 28, 2019	36,518	\$ 8.22	\$ 6.66	\$ 5.10
January 1, 2020	15,215	\$ 8.22	\$ 7.15	\$ 5.67
January 13, 2020	608	\$ 8.22	\$ 7.15	\$ 5.67
January 22, 2020	2,434	\$ 8.22	\$ 7.15	\$ 5.67
February 26, 2020	3,651	\$ 8.22	\$ 7.15	\$ 5.67
March 1, 2020	3,043	\$ 8.22	\$ 7.15	\$ 5.67
March 2, 2020	2,434	\$ 8.22	\$ 7.15	\$ 5.67
March 4, 2020	114,845	\$ 8.22	\$ 7.15	\$ 5.67
March 16, 2020	10,346	\$ 8.22	\$ 7.15	\$ 5.67
March 23, 2020	3,651	\$ 8.22	\$ 7.15	\$ 5.67
May 7, 2020	12,172	\$ 13.72	\$ 13.72	\$ 10.68
June 23, 2020	9,129	\$ 13.72	\$ 13.72	\$ 10.68

**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 on each grant date:

<b>Grant Date</b>	<b>Number of Shares Subject to SARs Granted</b>	<b>Per Share Base Price of SARs</b>	<b>Fair Value per Share on Grant Date</b>	<b>Per Share Estimated Fair Value of SARs on Grant Date</b>
January 7, 2019	40,165	\$ 8.22	\$ 4.28	\$ 3.29
April 22, 2019	6,086	\$ 8.22	\$ 5.34	\$ 4.11
June 23, 2020	9,129	\$ 13.72	\$ 13.72	\$ 10.68

## **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 June 30, 2020 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 30<sup>th</sup> 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 June 30, 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 June 30, 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 June 30, 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 six months ending June 30, 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 living with rare neurological disorders who have 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 H<sub>3</sub> receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of 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, following receipt of a Complete Response Letter, or CRL, for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in our New Drug Application, or NDA, in support of the adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020. 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 H<sub>3</sub> 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, which we plan on submitting in the second half of 2020. 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 symptoms. 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 by Rush University Medical Center 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 H<sub>3</sub> receptor antagonist/inverse agonist approved by the FDA. It is approved 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 waking.** 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 living with rare neurological disorders who have 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, following receipt of a CRL for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that were submitted in the NDA in support of the adult cataplexy indication. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication. We expect to submit this resubmission during the third quarter of 2020.
- **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 for PWS 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, which we plan on submitting in the second half of 2020. 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 June 30, 2020, over 1,750 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 2,700 unique patients (out of the approximately 42,000 diagnosed and treated narcolepsy patients in the United States). We have secured formulary access for over 166 million lives, which represents 70% 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, and for the three months ended June 30, 2020, net sales of WAKIX were \$38.0 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 19 years of age or under. We believe that 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, following receipt of a CRL for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that were submitted in the NDA in support of the adult cataplexy indication. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. 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. We

expect to submit the complete response resubmission during the third quarter of 2020, and depending on the timing and outcome of the FDA's subsequent review, the FDA could make a decision on the adult cataplexy indication as early as the second half of 2020. If the FDA requires us to conduct additional trials to gain a cataplexy indication in adult patients with narcolepsy following our resubmission, we anticipate that any such clinical trials 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 in adult patients with narcolepsy 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."

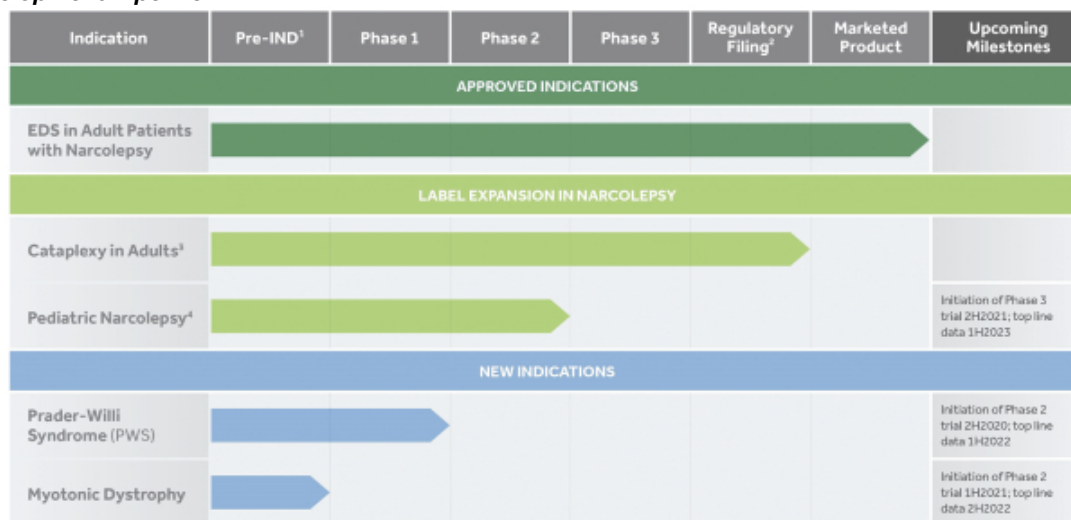
### **Additional Indications**

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 H<sub>3</sub> 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 H<sub>3</sub> 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. 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 IND, which we plan on submitting in the second half of 2020.

**Overview of Development Pipeline**



1. 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 WAKIX. 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 CRL for the adult cataplexy indication in August 2019. Subsequently, we received a general advice letter from the FDA in June 2020 stating that the FDA had reanalyzed data from the HARMONY 1 trial that we submitted in our NDA in support of an adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission in the third quarter of 2020.  
 4. 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.

## [Table of Contents](#)

- **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 June 30, 2020, we have secured formulary access covering approximately 166 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 waking.

### **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 H<sub>3</sub> receptor. It activates histaminergic neurons in the brain, a neuronal system involved in the maintenance of wakefulness, attention, vigilance and cognition. Pitolisant binds to H<sub>3</sub> 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 H<sub>1</sub> 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 H<sub>3</sub> 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.

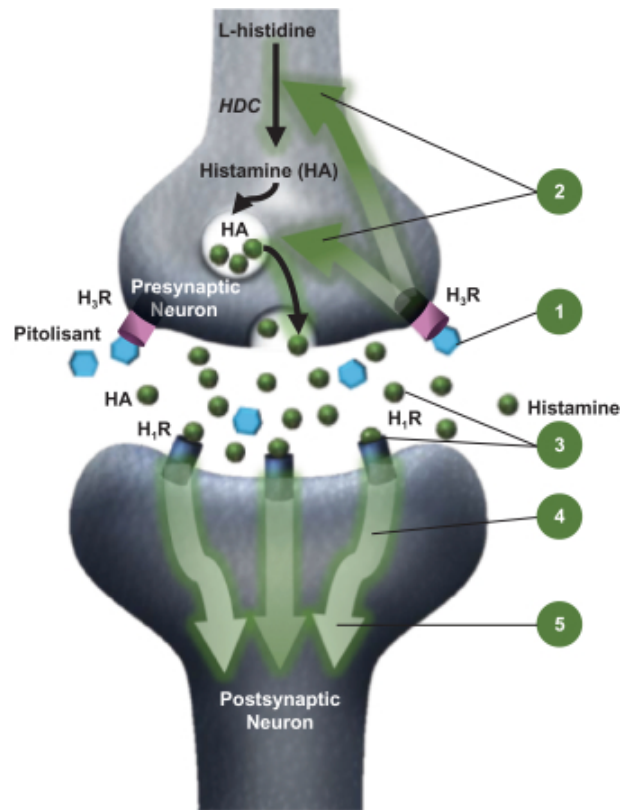
### WAKIX® (pitolisant) Mechanism of Action

**Pitolisant is a histamine H<sub>3</sub>-receptor antagonist / inverse agonist that enhances the activity of histaminergic neurons in the brain**

1. Pitolisant binds to presynaptic H<sub>3</sub> autoreceptors, which blocks histamine binding to these receptors and increases histamine release from presynaptic neurons
2. Acting as an inverse agonist, pitolisant initiates increased histamine synthesis and release from vesicles into the synapse
3. This increased histamine in the synapse is then available to bind to excitatory postsynaptic H<sub>1</sub> receptors
4. Increased histamine binding at H<sub>1</sub> receptors results in an increase in neuronal firing of postsynaptic neurons
5. Increased firing of histamine neurons further activates wake-associated brain regions and further inhibits non-REM and REM sleep-associated brain regions

HA = Histamine; HDC = L-histidine decarboxylase;  
H<sub>3</sub>R = Histamine 3 Receptor; H<sub>1</sub>R = Histamine 1

Receptor Figure adapted from: Benarroch EE.  
*Neurology*. 2010;75(16):1472-1479.



## Table of Contents

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.

	<b>Trial Design</b>	<b>Number of Patients; % with Cataplexy</b>	<b>Maximum Dose; % at that Dose</b>	<b>Primary Endpoint</b>	<b>Results</b>
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; <sup>3</sup> 1 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 1bis 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 1bis), 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 initially 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 CRL with respect to the cataplexy indication, and therefore did not approve WAKIX for the treatment of cataplexy in adult patients with narcolepsy. Subsequently, in June 2020, in response to our request for FDA to reconsider the cataplexy data from the HARMONY 1 trial, we received a general advice letter from the FDA stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in our NDA in support of the adult cataplexy indication for WAKIX. The general advice letter stated that the FDA confirmed that the cataplexy data from the HARMONY 1 clinical trial supported a statistically significant reduction in daily rate of cataplexy in the pitolisant group when compared with the placebo group. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission in the third quarter of 2020.
- 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.

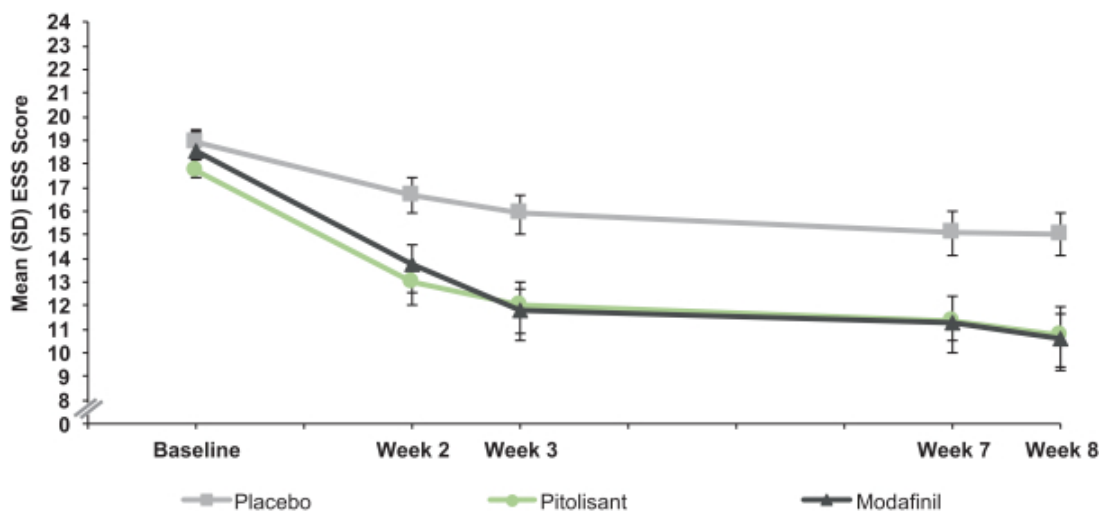
The primary endpoint in the trial was the ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo. ESS is a self-administered eight-item questionnaire scored 0 to 24 with lower

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.

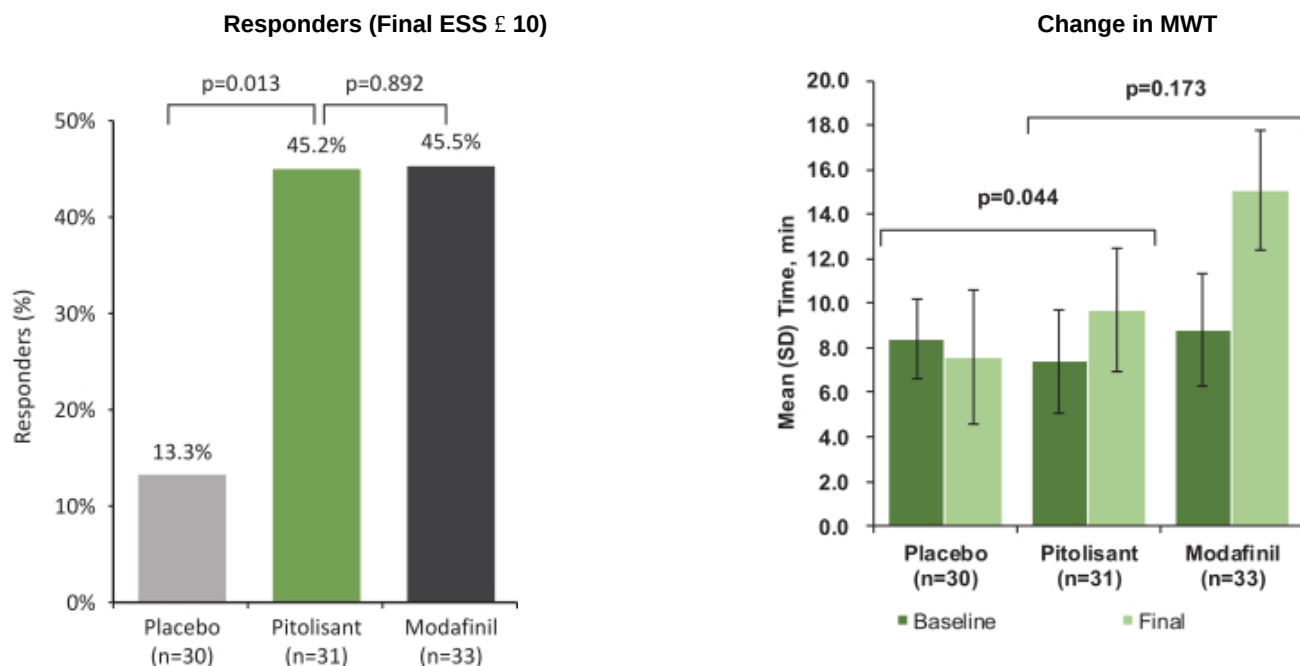
*Efficacy Results*

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  $\leq 10$ ) 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 ( $p=0.173$ ).



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 no 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.

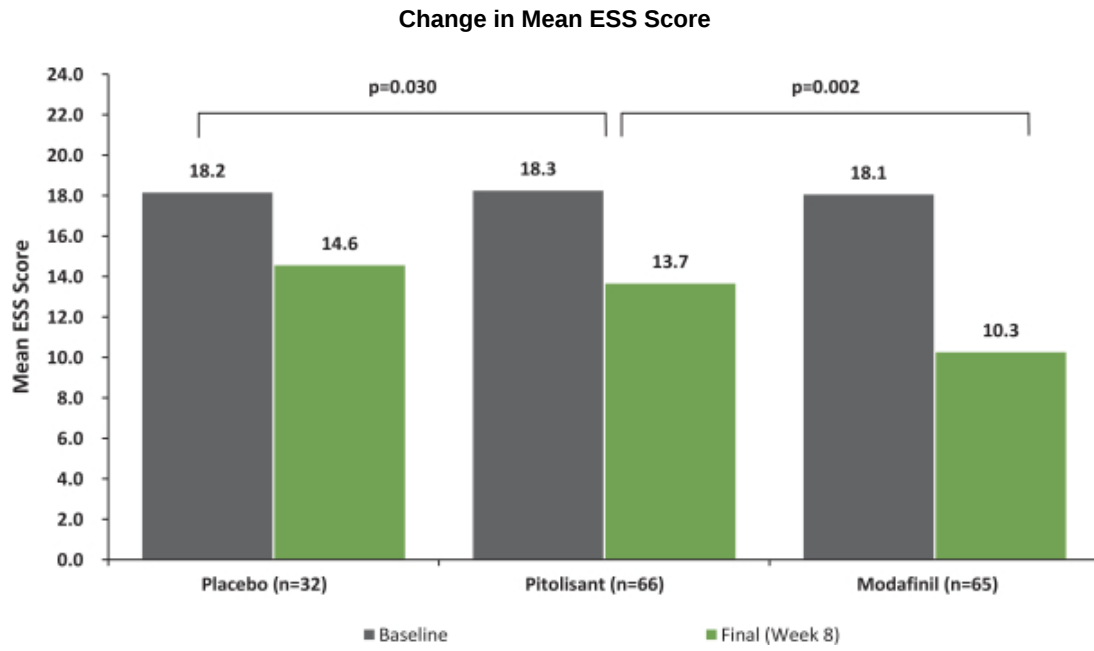
### **HARMONY 1bis**

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.

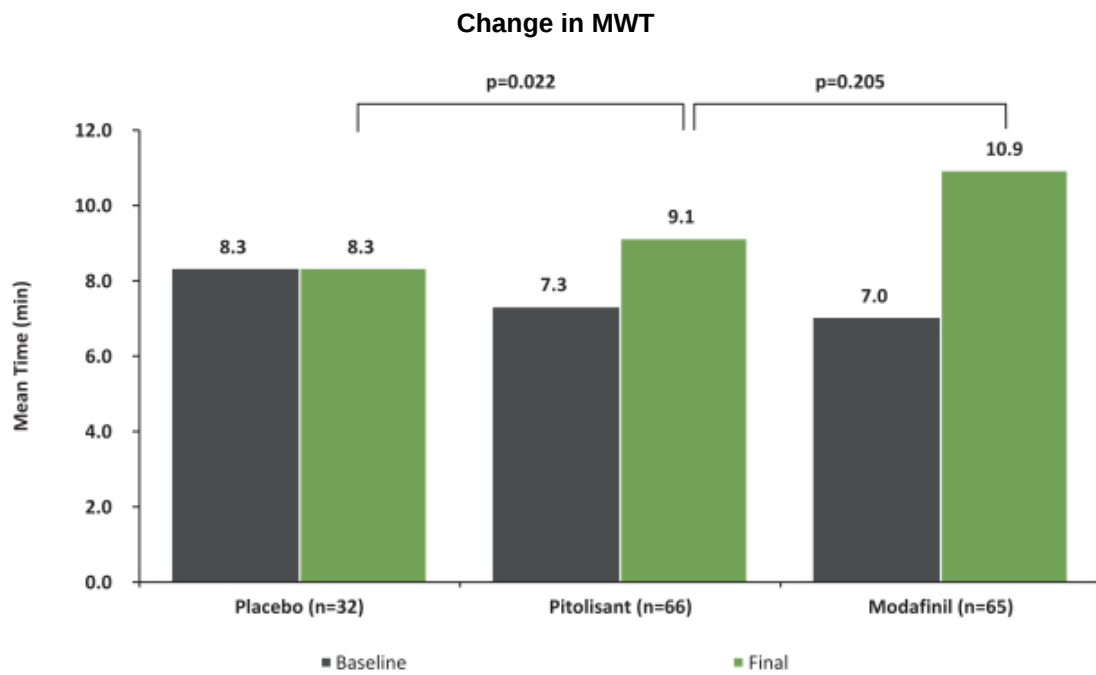
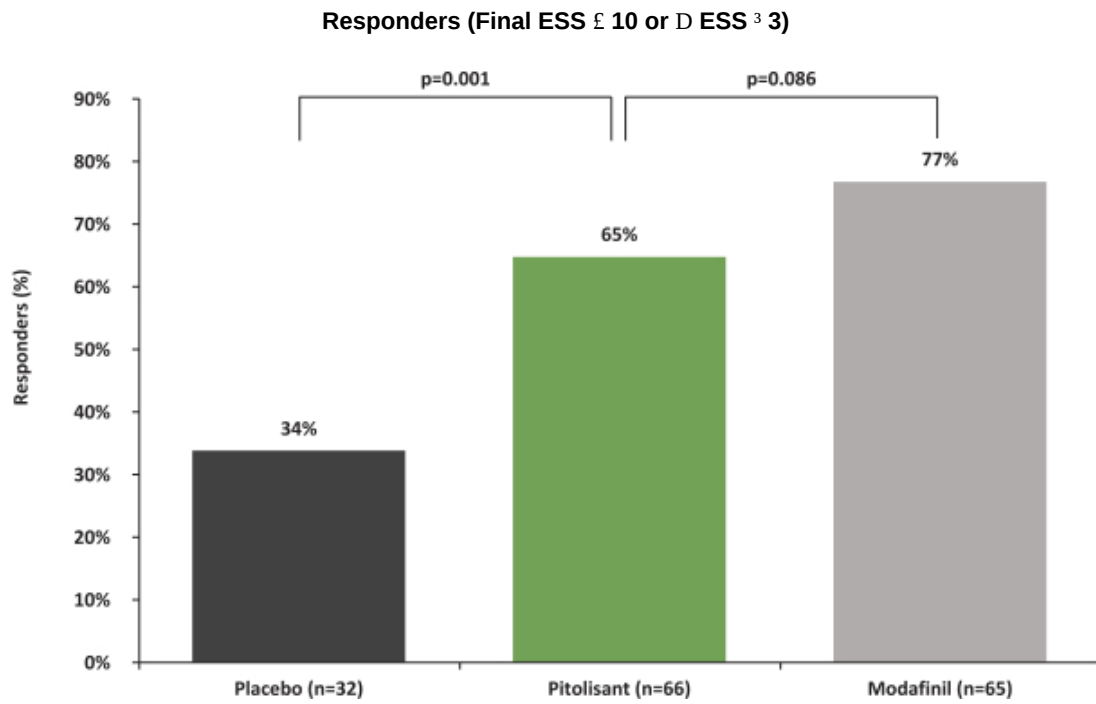
The primary endpoint in the trial was the ESS score at final visit, adjusted for baseline, for pitolisant compared to placebo. Secondary endpoints included ESS responder rates, MWT, SART, reduction in cataplexy, CGI-C for both EDS and cataplexy, the EQ-5D, and the Patient's Global Opinion on the Effect 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.



Regarding the secondary endpoints, ESS responder rates (a responder was defined as having a final ESS score  $\leq 10$  or change in ESS score  $\geq 3$ ) 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 no prospective plan to control for Type 1 error in this trial.



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



## [Table of Contents](#)

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*

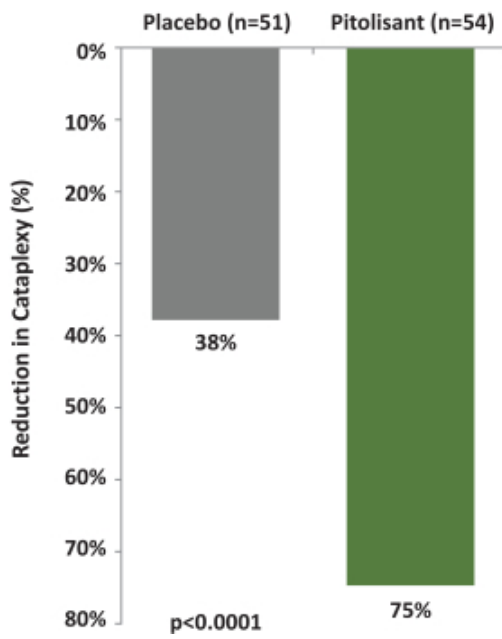
HARMONY CTP was a randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of pitolisant on the reduction in cataplexy in adult patients with narcolepsy with frequent attacks of cataplexy over a seven-week period. HARMONY CTP consisted of 106 patients. The maximum dose of 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.

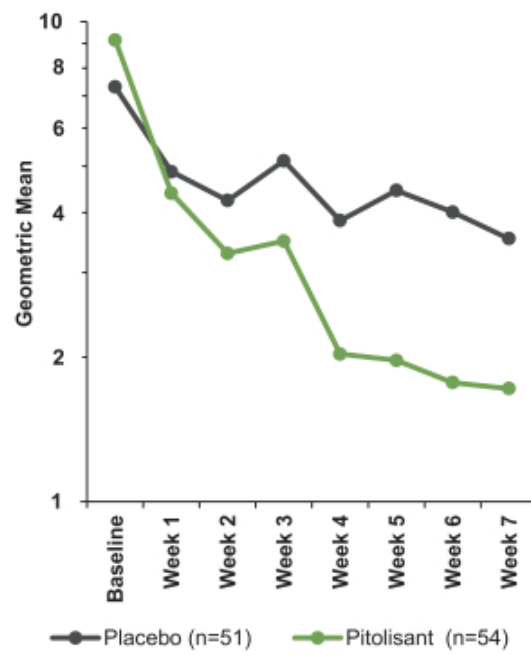
### *Efficacy Results*

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 (rate ratio (95% CI) 0.512 (0.435, 0.603);  $p<0.0001$ ). 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  $3.5\pm 1.1$  with placebo versus  $2.6\pm 1.1$  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.

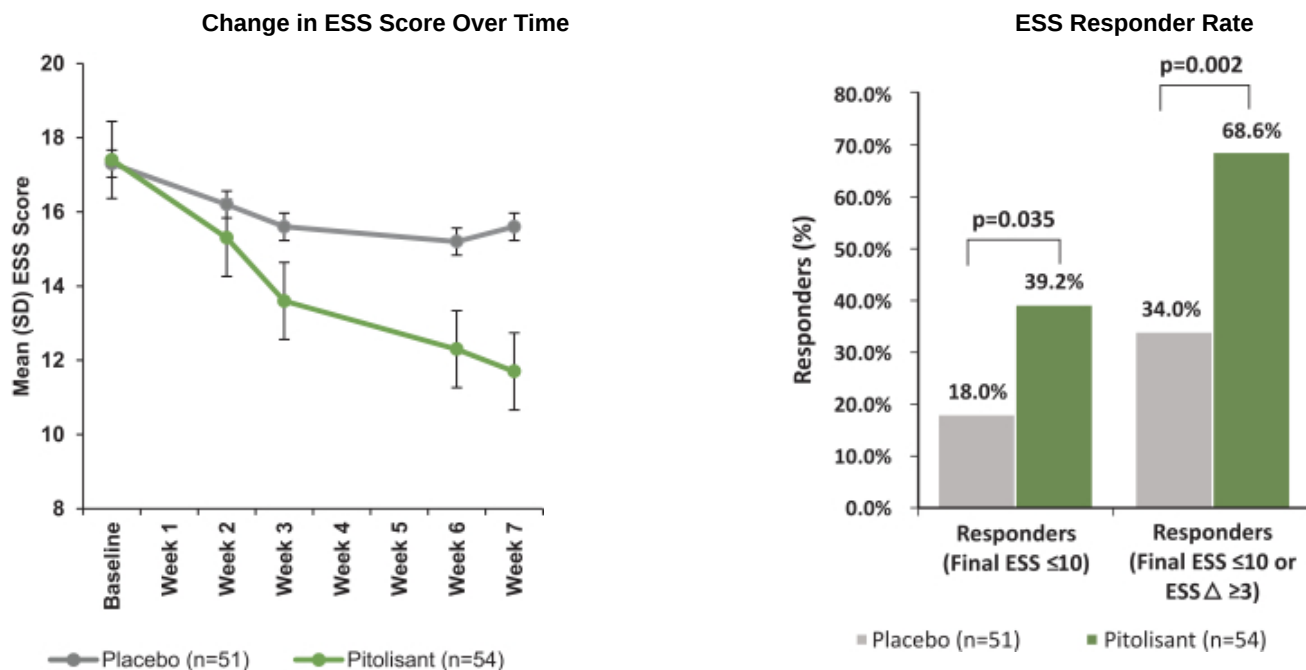
**Percent Reduction in WRC**



**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 no 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**

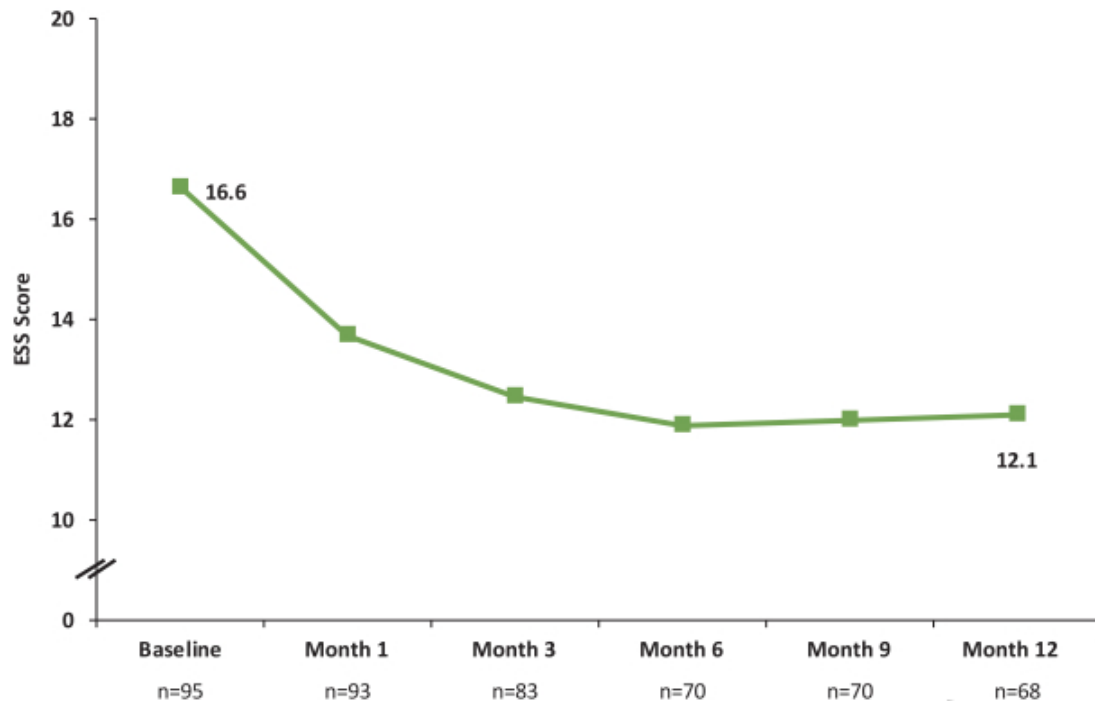
*Design*

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*

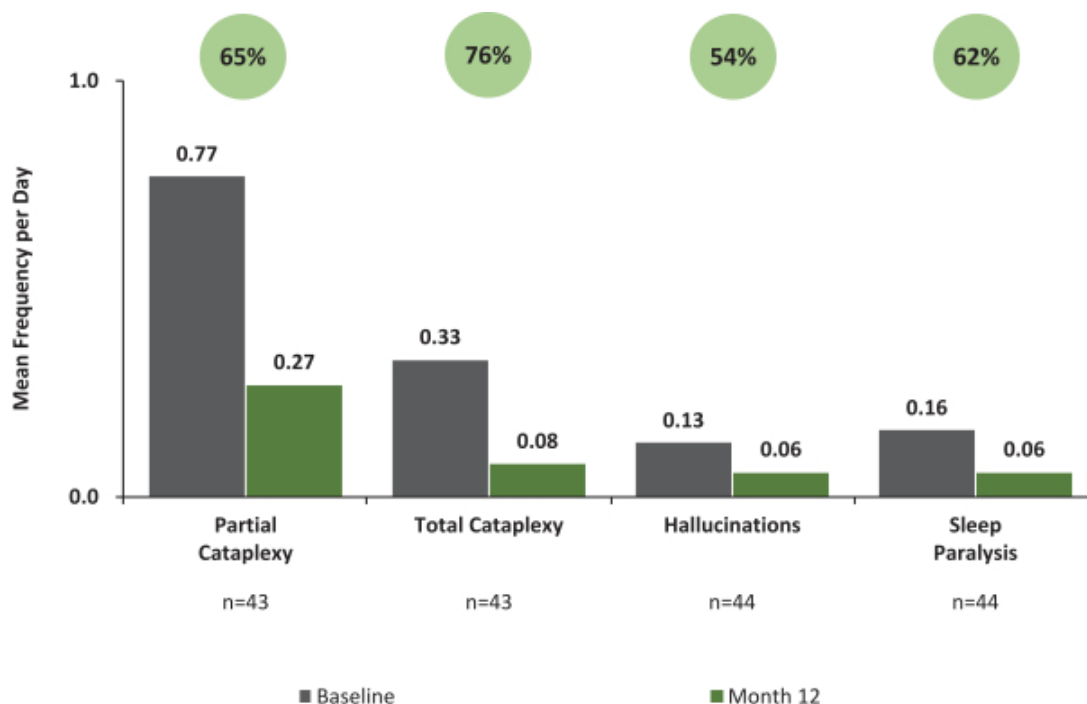
In the 68 patients with data at baseline and at 12 months in HARMONY 3, pitolisant reduced the mean ESS score by -4.63 over this period. The magnitude of the decrease in ESS score was larger in the subgroup of patients (n=86) who were not on pitolisant at trial entry (-5.25) as compared to the subgroup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

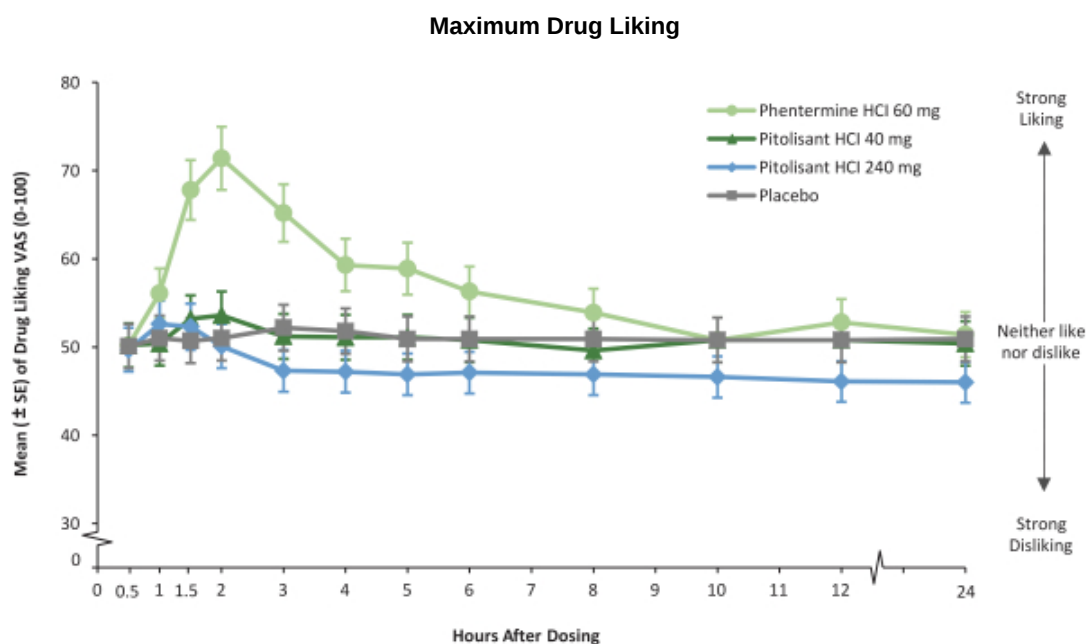
### Clinical HAP Trial

#### 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 ( $E_{max}$ ) on the 100-point Drug Liking (at the moment) visual analog scale.

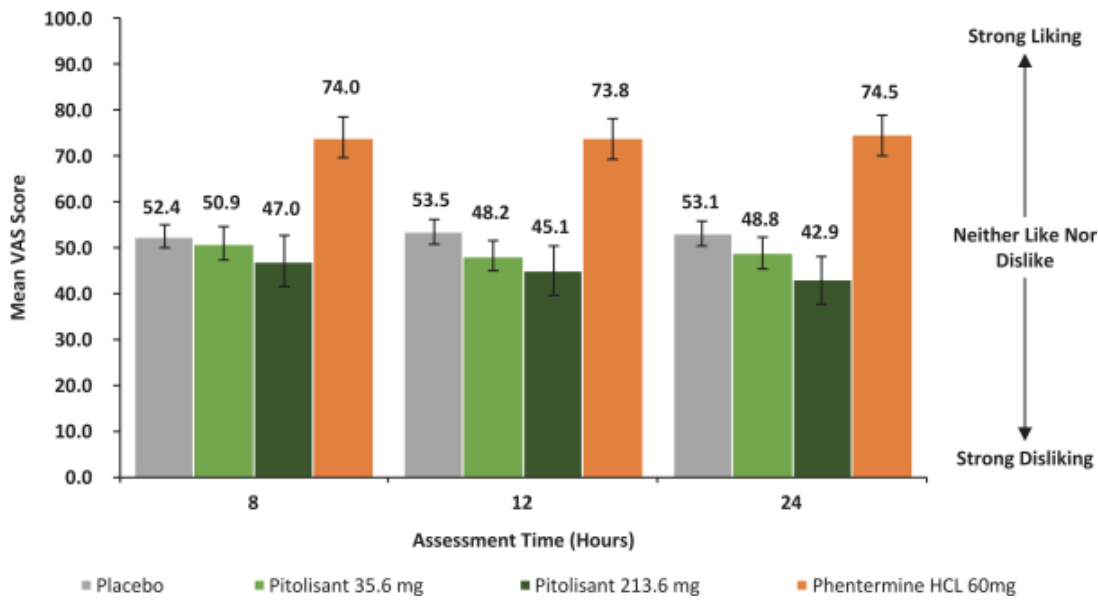
#### Results

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).

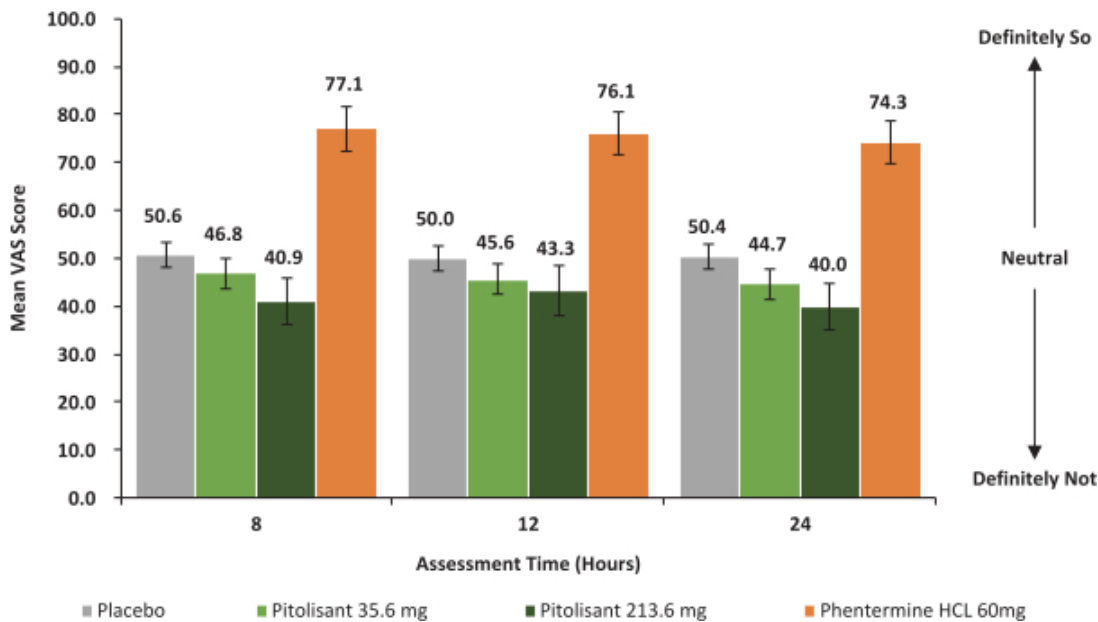


Similarly, for key secondary measures of Overall Drug Liking and willingness to Take Drug Again, mean  $E_{max}$  scores were significantly greater for phentermine (77.4 for Overall Drug Liking and 78.7 for Take Drug Again) versus pitolisant 213.6 mg (49.3 and 44.5) and 35.6 mg (52.7 and 49.4) ( $p 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

## Post-Hoc Analyses for Pitolisant

We conducted three post-hoc analyses from the database of pooled clinical trial results for pitolisant, which focused on clinically relevant aspects of the product profile. The first involved an analysis of the time-to-response for pitolisant on both improvement in EDS and reduction in cataplexy based on pooled data from the HARMONY 1, HARMONY 1bis, and HARMONY CTP randomized, controlled clinical trials. Pitolisant was titrated to a maximum dose of 35.6 mg/day (HARMONY 1, HARMONY CTP) or 17.8 mg/day (HARMONY 1bis). The change from baseline in mean ESS score (in all three studies) and mean weekly rate of cataplexy (WRC; in HARMONY CTP) was compared for pitolisant versus placebo. In the higher-dose HARMONY 1 (pitolisant, n=31; placebo, n=30) and HARMONY CTP (pitolisant, n=54; placebo, n=51) trials, the ESS score improvement was significantly greater with pitolisant versus placebo beginning at Week 2 (LS mean difference, -2.8; p=0.015) and Week 3 (LS mean difference, -2.0; p=0.005), respectively. In the lower-dose HARMONY 1bis trial (pitolisant, n=66; placebo, n=32), significant separation from placebo was first observed at Week 7 (LS mean difference, -2.3; p=0.044). In HARMONY CTP, the LS mean WRC with pitolisant was 11.7 at baseline, 4.6 at end-of-treatment, and 5.1 after a one-week, placebo-washout period. Improvement in the WRC was significantly greater with pitolisant versus placebo beginning at Week 2 (LS mean difference, -5.3; p=0.004) and continued through end-of-treatment (LS mean difference, -6.2; p<0.001); there was no evidence of rebound cataplexy after placebo-washout (LS mean difference, -4.9; p=0.027). These analyses demonstrate that the time-to-response for pitolisant for both improvement in EDS and reduction in cataplexy began within the first few weeks of treatment and was more robust in patients who are titrated to the maximum dose of 35.6 mg/day compared to a dose of 17.8 mg/day. The rate of cataplexy attacks decreased early during treatment, with no evidence of rebound when pitolisant was withdrawn.

A second post-hoc analysis evaluated the efficacy of pitolisant in patients with narcolepsy who had a high symptom burden (both EDS and cataplexy) at baseline; this analysis was based on pooled data from both the HARMONY 1 and HARMONY CTP clinical trials, in which patients could be titrated up to a maximum dose of 35.6 mg/day. The analyses included three independent patient subgroups: baseline score of >16 on the ESS, sleep latency of  $\leq$ 8 minutes on MWT, and  $\geq$ 15 cataplexy attacks per week. The analysis populations included 108 patients for the ESS (pitolisant, n=54; placebo, n=54), 105 for the MWT (pitolisant, n=59; placebo, n=46), and 31 for cataplexy (pitolisant, n=20; placebo, n=11). Mean change in ESS from baseline was significantly greater for pitolisant (-6.1) compared with placebo (-2.6; p=0.0002). A significantly greater percentage of pitolisant-treated patients were classified as treatment responders: for ESS score reduction  $\geq$ 3, 68.5% in the pitolisant group versus 35.2% in the placebo group (p=0.0006); for final ESS score  $\leq$ 10, 35.2% versus 9.3%, respectively (p=0.0026). Mean increase in sleep latency on the MWT was significantly greater for pitolisant (7.0 minutes) compared with placebo (3.4 minutes; p=0.0089). Decrease in mean weekly rate of cataplexy was significantly greater for pitolisant (baseline, 21.8; final, 3.9) compared with placebo (baseline, 20.9; final, 18.2); the rate ratio was 0.35 (95% CI, 0.26–0.47; p<0.001). Adverse events in the analysis populations were consistent with the known safety profile of pitolisant; headache was the most common adverse event in pitolisant-treated patients (10.0%–20.4%). These analyses demonstrated pitolisant resulted in significant improvement for patients who experience a high burden of the two most common symptoms in narcolepsy, EDS and cataplexy.

In the third post-hoc analysis, we evaluated the cardiac safety events associated with pitolisant because cardiovascular diseases are comorbid conditions in patients with narcolepsy. Cardiovascular adverse effects are of concern with narcolepsy medications because of this comorbidity and most patients require lifelong pharmacotherapy for both narcolepsy and cardiovascular disorders. Data were obtained from a pooled analysis of the HARMONY 1 (8-week) and HARMONY CTP (7-week) clinical trials and from the 12-month, open-label HARMONY 3 trial. The pooled analysis included 166 patients (pitolisant, n=85; placebo, n=81). Mean change in heart rate from baseline to end-of-treatment was -0.5 beats/min with pitolisant and -0.2 beats/min with placebo (LS mean difference, -0.4; p=0.744).

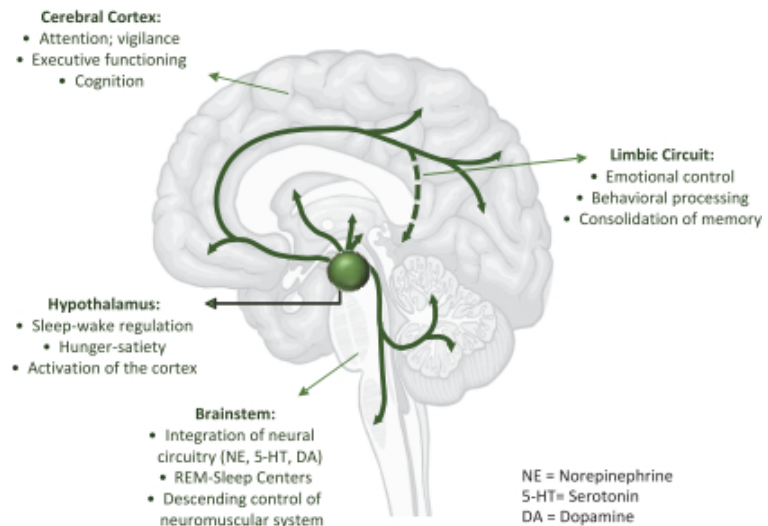


Mean change was also similar for pitolisant versus placebo in systolic (LS mean difference, 0.0;  $p=0.983$ ) and diastolic (LS mean difference,  $-0.6$ ;  $p=0.552$ ) blood pressure, as was mean change in QTc interval (LS mean difference, 0.4;  $p=0.911$ ). Cardiac adverse events with pitolisant included heart rate increase ( $n=4$ ), right bundle branch block ( $n=1$ ), sinus tachycardia ( $n=1$ ), and palpitations ( $n=1$ ), and with placebo included blood pressure increase ( $n=1$ ). In the long-term study, mean change from baseline in QTc interval was 3.1 msec at Month 6 ( $n=70$ ) and 6.1 msec at Month 12 ( $n=67$ ); three patients had a post-baseline increase  $>60$  msec but none had QTc  $>500$  msec. Based on this analysis, no cardiac safety signals were observed during treatment with pitolisant administered up to the maximum dose of 35.6 mg and for up to one year. Because concomitant use of pitolisant with other drugs known to increase the QT interval may add to the QT effects of pitolisant, it should not be used in combination with these medications.

### 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, following receipt of a CRL for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 trial that were submitted in the NDA in support of the adult cataplexy indication. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020. 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 H<sub>3</sub> 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 H<sub>3</sub> 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, H<sub>3</sub> 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 H<sub>3</sub> receptor (as opposed to H<sub>1</sub> receptors, H<sub>2</sub> receptors and H<sub>4</sub> receptors), is the reason, we believe, for pitolisant's unique MOA and why it works very differently than anti-histamines (peripheral H<sub>1</sub> receptor blockers) or anti-ulcer medications (H<sub>2</sub> receptor blockers).

- Role of histamine in normal physiologic functioning beyond wake promotion (e.g. attention, vigilance, behavior, cognition)
- Location of H<sub>3</sub> receptors in hypothalamus, brainstem, and cerebral cortex account for different functions (and potential symptoms in different disorders)
- Limited H<sub>3</sub> 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 for PWS 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, pending authorization to proceed under an IND which we plan on submitting in the second half of 2020, 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 CTP and HARMONY 1. 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, which we provided to the FDA. Following these interactions, we received a general advice letter from the FDA in June 2020 stating that the FDA had re-analyzed data from the HARMONY 1 clinical trial that we submitted in the NDA in support of the adult cataplexy indication for WAKIX. The general advice letter states that the FDA confirmed that the cataplexy data from the HARMONY 1 clinical trial supported a statistically significant reduction in daily rate of cataplexy in the pitolisant group when compared with the placebo group. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. We expect to submit this resubmission during the third quarter of 2020.

### *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 for PWS 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 and no FDA-approved treatments for EDS in patients with PWS. 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 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. The primary symptom in patients with MD is myotonia, which is an impairment in the ability of muscles to relax, which results in progressive muscle weakness. 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. EDS and fatigue occur in approximately 80% to 90% of 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 H<sub>3</sub> 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. There are currently no FDA-approved treatments for patients with MD, which represents a significant unmet medical need.

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, which we plan on submitting in the second half of 2020.

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 announced the FDA approval of a lower/low sodium formulation of Xyrem, with an expected commercial launch in the fourth quarter of 2020, 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

## [Table of Contents](#)

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.

## [Table of Contents](#)

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](http://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.

## [Table of Contents](#)

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.

## [Table of Contents](#)

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

## [Table of Contents](#)

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

## [Table of Contents](#)

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 anti-kickback 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 June 30, 2020, we have approximately 150 employees, 98 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)
<b>Executive Officers</b>		
John C. Jacobs	53	President and Chief Executive Officer, Director
Susan L. Drexler	51	Chief Financial Officer
Jeffrey Dayno, M.D.	63	Chief Medical Officer
Jeffrey Dierks	49	Chief Commercial Officer
Andrew Serafin	46	Chief Business Officer
<b>Non-Employee Directors</b>		
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
Gary Sender	58	Director
Andreas Wicki, Ph.D.	61	Director

\* Dr. Edwards and Dr. Royston will resign as directors immediately prior to the effectiveness of the registration statement on Form S-1, of which this prospectus forms a part.

### Executive Officers

**John C. Jacobs.** Mr. Jacobs has served as our President and 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

## [Table of Contents](#)

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 Clarity 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., a public biopharmaceutical company, Karus Ltd., F2G Ltd., and Vantia Therapeutics Ltd. He is also independent chairman of the board of directors of public biopharmaceutical company KalVista Pharmaceuticals, Inc., and an independent board member of Reata Pharmaceuticals, Inc. and 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, MacuLogix, Inc. since March 2019, and ALX Oncology Limited since April 2020. 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 Managing 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 previously served on the board of directors of Akero Therapeutics, a public biotechnology company, and 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.

**Gary Sender.** Mr. Sender has served as a member of our board of directors since August 2020. Mr. Sender has served as Chief Financial Officer of Nabriva Therapeutics plc, or Nabriva, a publicly traded biopharmaceutical company engaged in the commercialization and development of innovative

## [Table of Contents](#)

anti-infective agents to treat serious infections, since May 2016. Prior to joining Nabriva, Mr. Sender served as Chief Financial Officer and Executive Vice President at Synergy Pharmaceuticals Inc., or Synergy, a publicly traded biopharmaceutical company, from November 2015 to April 2016. Prior to joining Synergy, from August 2009 to June 2015, Mr. Sender served as Senior Vice President, Finance at Shire plc, or Shire, a biopharmaceutical company since acquired by Takeda Pharmaceutical Company Limited, supporting its Specialty Pharmaceuticals business and subsequently its Global Commercial businesses. Prior to joining Shire, Mr. Sender served as founding Chief Financial Officer of Tengion, Inc., a regenerative medicine company, from August 2004 to July 2009. Mr. Sender also spent over 15 years in several leadership roles within Merck & Co., Inc., a publicly traded pharmaceutical company. Mr. Sender currently serves on the board of Schrödinger, Inc. and is the Chairman of their Audit and Compensation Committees. Mr. Sender received a B.S. in Finance from Boston University and an M.B.A. from Carnegie-Mellon University. We believe that Mr. Sender is qualified to serve on our board of directors because of his extensive finance and life sciences industry experience, as well as 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 nine directors. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the number of directors on our board of directors will be fixed from time to time by resolution of the board of 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 and Dr. Royston will resign as 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.

## [Table of Contents](#)

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be Messrs. Aronin and Jacobs, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be Messrs. Sabater and Sender, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors will be Messrs. Gracias, Nielsen and Wicki, and their terms will expire at the annual meeting of stockholders to be held in 2023.

### **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. Gracias, Nielsen, Sabater, Sender and Wicki 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

## [Table of Contents](#)

- 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. Nielsen, Sender and Wicki, with Mr. Sender serving as chair. Rule 10A-3 of the Exchange Act and the Nasdaq 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 affirmatively determined that Messrs. Nielsen, Sender and Wicki each meet the definition of “independent director” for purposes 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 Nasdaq listing standards. In addition, our board of directors has determined that Mr. Sender will qualify as an “audit committee financial expert,” as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors has adopted a new written charter for the audit committee, which will be available on our principal corporate website at [www.harmonybiosciences.com](http://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. Nielsen and Sabater, with Mr. Sabater serving as chair. Our board of directors has adopted a new written charter for the nominating and corporate governance committee, which will be available on our principal corporate website at [www.harmonybiosciences.com](http://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 corporate goals and objectives with respect to the compensation of our Chief Executive Officer, evaluating our Chief Executive Officer’s performance in light of these goals and objectives and setting compensation;
- reviewing and setting or making recommendations to our board of directors regarding the compensation of our other executive officers;
- reviewing and making recommendations to our board of directors regarding director compensation;
- reviewing and approving or making recommendations to our board of directors regarding our incentive compensation and equity-based plans and arrangements; and
- appointing and overseeing any compensation consultants.

## [Table of Contents](#)

Upon the consummation of this offering, our compensation committee will consist of Messrs. Gracias, Sender and Wicki, with Mr. Gracias serving as chair. Our board has determined that Messrs. Gracias, Sender and Wicki are “non-employee directors” as defined in Section 16b-3 of the Exchange Act. Our board of directors has adopted a new written charter for the compensation committee, which will be available on our principal corporate website at [www.harmonybiosciences.com](http://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](http://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, President and 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.

<b>Name and Principal Position</b>	<b>Salary (\$)</b>	<b>Bonus \$(1)</b>	<b>Option Awards \$(2)</b>	<b>All Other Compensation \$(3)</b>	<b>Total (\$)</b>
John C. Jacobs <i>President and Chief Executive Officer</i>	454,000	391,575	—	88	845,663
Jeffrey Dayno <i>Chief Medical Officer</i>	414,000	238,050	20,000	148	672,175
Andrew Serafin <i>Chief Business Officer</i>	340,500	195,788	—	754	537,042
John Vittoria <i>former Chief Financial Officer</i>	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 Holdings, Inc. Amended and Restated 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.

<u>Named Executive Officer</u>	<u>Number of Shares Subject to Options Granted in 2019</u>
Jeffery Dayno	6,086

In connection with this offering, our board of directors adopted, and our stockholders approved, the 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 our subsidiaries and to enable our Company and our subsidiaries to obtain and retain services of these individuals, which is essential to our long-term success. Upon the effectiveness of the 2020 Plan, no further grants will be made under the Equity Incentive Plan. However, the Equity Incentive Plan will continue to govern the terms and conditions of outstanding awards granted under it. For additional information about the 2020 Plan, please see the section titled "—Executive Compensation Plans—2020 Incentive Award Plan" below.



### ***IPO-Related Equity Grants***

Our board of directors approved the grant of stock options pursuant to the 2020 Plan to certain of our directors, consultants and employees, including our named executive officers (other than Mr. Vittoria), in connection with this offering. These stock option grants will become effective immediately following the determination of the initial public offering price per share of our common stock, and each will have a per share exercise price equal to that initial public offering price.

The stock options granted to our consultants and employees will cover, in the aggregate, 1,300,619 shares of our common stock, and will vest as to one-fifth of the shares underlying the option on each of the first five anniversaries of the date on which this offering is consummated, subject to the grantee's continued employment (or service, as applicable) through the applicable vesting date. Of these, the stock options to be granted to Messrs. Jacobs, Dayno and Serafin will cover 144,856, 132,260 and 81,875 shares of our common stock, respectively.

The number of shares of our common stock subject to stock options to be granted to certain of our directors, other than Mr. Aronin, will be determined based on the initial public offering price per share of our common stock in this offering. These options are further described under the section titled, "Director Compensation—Director IPO Grants" 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 through 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.

Name	Grant Date	Vesting Commencement Date (1)	Option Awards			
			Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
John C. Jacobs	10/2/2017	10/1/2017	125,900	188,850	\$ 8.22	10/2/2027
	10/1/2018	10/1/2018	24,345	97,382	\$ 8.22	10/1/2028
Jeffery Dayno	11/13/2017	11/1/2017	41,387	62,081	\$ 8.22	11/13/2028
	1/7/2019	1/1/2019	—	6,086	\$ 8.22	1/7/2029
Andrew Serafin	10/1/2017	10/1/2017	48,691	73,037	\$ 8.22	10/1/2027
	10/1/2018	10/1/2018	3,651	14,607	\$ 8.22	10/1/2028
John Vittoria	11/14/2018	11/1/2018	9,738	—	\$ 8.22	2/28/2020

- (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, which will be amended and restated effective upon the completion of this offering. 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 as in effect in 2019, 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. Under the agreement, and as amended and restated, his annual base salary is \$473,068. 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 as in effect in 2019, 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

## [Table of Contents](#)

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 as amended and restated 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.

## [Table of Contents](#)

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.

### **Separation Plan**

In June 2020, our board of directors adopted the Harmony Biosciences, LLC Separation Plan (the "Separation Plan"), which provides for the payment of certain severance and other benefits to eligible

## [Table of Contents](#)

employees, including certain of our named executive officers, following qualifying terminations of employment in connection with a “change in control” (as defined in the Separation Plan) of the Company. Messrs. Dayno and Serafin participate in the Separation Plan.

Under the Separation Plan, if during the period commencing on the 30th day immediately preceding the date on which a change in control is consummated and ending on the three-month anniversary of such change in control, (i) a participant’s employment is terminated by us without “cause” (excluding death or “disability”) or by the participant for “good reason” (each, as defined in the Separation Plan) and (ii) the participant is not offered a comparable position by an acquirer, then, we will pay or provide to the participant the following:

- (i) A lump sum cash payment, payable within 60 days following the termination date, equal to the sum of (A) the participant’s target bonus as in effect for the year in which the termination occurs, prorated for the portion of the year the participant was employed by us; (B) one half of the participant’s highest annual base salary as in effect during the 12-month period immediately preceding the termination date or the date of the change in control (whichever is earlier); and (C) the amount necessary to cover the full cost of healthcare coverage under our group health plans for a period of six months following the termination date; and
- (ii) Outplacement services for a period of 45 days.

A participant’s right to receive the severance payments and benefits described above is subject to his or her delivery and non-revocation of a general release of claims in our favor, and continued compliance with the restrictive covenants contained in the Separation Plan (which includes customary confidentiality and nondisparagement provisions, as well as standard non-compete and employee/customer non-solicitation restrictions effective during employment and for one year thereafter).

### **Director Compensation**

In 2019, we did not provide compensation to our non-employee directors.

### **Director IPO Grants**

In connection with this offering, our board of directors approved the grant of stock options pursuant to the 2020 Plan to certain of our non-employee directors. These stock option grants will become effective immediately following the determination of the initial public offering price per share of our common stock.

## Table of Contents

The Chairman of our board of directors, Jeff Aronin, will receive a stock option covering 1,259,611 shares of our common stock. Each of Messrs. Sender, Gracias, Nielson and Sabater will receive stock options with an aggregate value (determined using a Black-Scholes option value) as set forth in the table below. The number of shares of our common stock subject to these stock options will be determined based on the initial public offering price per share of our common stock in this offering. The following table presents the number of stock options that each such director will receive in connection with this offering, in each case, based on the midpoint of the price range for our common stock set forth on the cover page of the prospectus (\$21.50 per share), as well as the low and high points of the range.

<u>Non-Employee Director</u>	<u>Value of Options Granted</u>	<u>Number of Shares</u>		
		<i>Price Per Share - \$20.00</i>	<i>Price Per Share - \$21.50</i>	<i>Price Per Share - \$23.00</i>
Gary Sender	\$ 230,000	19,896	18,504	17,306
Antonio Gracias	\$ 175,000	15,138	14,079	13,168
Jack Nielson	\$ 125,000	10,813	10,056	9,406
Juan Sabater	\$ 125,000	10,813	10,056	9,406

These stock options will have a per share exercise price equal to that initial public offering price, and will vest as to one-third of the shares underlying the option on each of the first three anniversaries of the date on which this offering is consummated, subject to continued service through the applicable vesting date; however, Mr. Aronin's option will vest as to one-fifth of the shares on each of the first five anniversaries of the date on which this offering is consummated, subject to continued service through the applicable vesting date.

### **Post-IPO Director Compensation Program**

In connection with this offering, our board of directors adopted and our stockholders approved a nonemployee director compensation program (the "Director Compensation Program"), which will become effective in connection with the completion of this offering. The Director Compensation Program provides for annual retainer fees and long-term equity awards for certain of our non-employee directors other than Andreas Wicki (each, an "Eligible Director"). Jeff Aronin, the Chairman of our board of directors, only will be eligible to receive cash compensation under the Director Compensation Program. The material terms of the Director Compensation Program are summarized below.

The Director Compensation Program consists of the following components:

#### Cash Compensation:

- Annual Retainer: \$45,000
- Annual Committee Chair Retainer:
  - o Audit: \$20,000
  - o Compensation: \$15,000
  - o Nominating and Corporate Governance: \$10,000
- Annual Committee Member (Non-Chair) Retainer:
  - o Audit: \$10,000
  - o Compensation: \$8,000
  - o Nominating and Corporate Governance: \$5,000
- Annual Non-Executive Chairman of the Board Retainer: \$40,000

Annual cash retainers will be paid in quarterly installments in arrears and will be pro-rated for any partial calendar quarter of service.

## [Table of Contents](#)

### Equity Compensation:

*Initial Grant:* Each Eligible Director who is initially elected or appointed to serve on the Board after the effective date of this offering automatically shall be granted, on the date on which such Eligible Director is appointed or elected to serve on the Board, a stock option to purchase shares of our common stock with a value (determined using a Black-Scholes option value) as set forth below:

- Audit Committee Chair: \$230,000
- Compensation Committee Chair: \$175,000
- Nominating and Corporate Governance Chair: \$125,000
- Eligible Director (Non-Chair): \$125,000

Each Initial Grant will vest in substantially equal installments on each monthly anniversary of the applicable grant date, such that the award is fully vested on the third anniversary of the grant date, subject to such Eligible Director's continued service through the applicable vesting date.

*Annual Grant:* An Eligible Director who is serving on the Board as of the date of the annual meeting of the Company's stockholders each calendar year beginning with calendar year 2021 shall be granted, on such annual meeting date, a stock option to purchase shares of our common stock with a value (determined using a Black-Scholes option value) as set forth below:

- Audit Committee Chair: \$230,000
- Compensation Committee Chair: \$175,000
- Nominating and Corporate Governance Chair: \$125,000
- Eligible Director (Non-Chair): \$125,000

Each Annual Grant will vest in full on the earlier to occur of (i) the one-year anniversary of the applicable grant date and (ii) the date of the next annual meeting following the grant date, subject to continued service through the applicable vesting date.

In addition, each Initial Grant and Annual Grant will vest in full upon a change in control of our Company (as defined in the 2020 Plan).

Compensation under our Director Compensation Program will be subject to the annual limits on nonemployee director compensation set forth in the 2020 Plan, as described below.

### **Executive Compensation Plans**

The following summarizes the material terms of the long-term incentive compensation plan and employee stock purchase 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, which we amended and restated in connection with the consummation of this offering.

Under the Equity Incentive Plan as amended and restated, 4,320,876 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

## [Table of Contents](#)

Incentive Plan is 1,623,006 and no more than 432,087 shares may be granted to any one participant with respect to incentive stock options, or ISOs. The Equity Incentive Plan as amended and restated will expire in August 2030 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**

Our board of directors adopted, and our stockholders approved, the 2020 Incentive Award Plan, or the 2020 Plan, which will become effective in connection with the completion of this offering, 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 are summarized below.

*Eligibility and Administration.* Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries, are eligible to receive awards under the 2020 Plan. 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,

## [Table of Contents](#)

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 6,298,054 shares of our common stock is 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 35,000,000 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 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 clause (i) equal to 2,462,260 shares, and (ii) 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 lesser of (A) 4% 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. Dividend equivalents are only paid out to the extent that the vesting conditions of the underlying award are subsequently satisfied.

*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

## [Table of Contents](#)

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. If, however, the surviving entity assumes outstanding awards and, on or within 12 months of such change in control, a participant's employment is terminated by the Company (or the surviving entity or its affiliates) for any reason other than for cause (as defined in the 2020 Plan) or due to death or disability (as defined in the 2020 Plan), then all such awards will become fully vested and exercisable as of the date of such termination. 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.

### **2020 Employee Stock Purchase Plan**

In connection with the offering, our board of directors adopted, and our stockholders approved, the 2020 Employee Stock Purchase Plan, or the ESPP, which will become effective in connection with this offering. The material terms of the ESPP are summarized below.

*Shares Available; Administration.* A total of 629,805 shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2021 and ending in 2030, by an amount equal to the lesser of: (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors. In no event will more than 10,000,000 shares of our common stock be available for issuance under the ESPP.

Our board of directors or a committee designated by our board of directors will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the administrator of the ESPP.

*Eligibility.* The plan administrator may designate certain of our subsidiaries as participating "designated subsidiaries" in the ESPP and may change these designations from time to time. Employees of our company and our designated subsidiaries are eligible to participate in the ESPP if

## [Table of Contents](#)

they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under the ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

If the grant of a purchase right under the ESPP to any eligible employee who is a citizen or resident of a foreign jurisdiction would be prohibited under the laws of such foreign jurisdiction or the grant of a purchase right to such employee in compliance with the laws of such foreign jurisdiction would cause the ESPP to violate the requirements of Section 423 of the Code, as determined by the plan administrator in its sole discretion, such employee will not be permitted to participate in the ESPP.

Eligible employees become participants in the ESPP by enrolling and authorizing payroll deductions by the deadline established by the plan administrator prior to the relevant offering date. Directors who are not employees, as well as consultants, are not eligible to participate. Employees who choose not to participate, or are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

*Participation in an Offering.* We intend for the ESPP to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase our common stock through payroll deductions of up to 20% of their eligible compensation, which will include a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be 5,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant automatically will be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period.

Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such longer or shorter period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

*Transferability.* A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided in the ESPP.

## [Table of Contents](#)

*Certain Transactions.* In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2020 Plan.

*Plan Amendment; Termination.* The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP must be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP, or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code. The ESPP will remain in effect until 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:

<b>Stockholder</b>	<b>Shares of Series A Stock</b>	<b>Total Purchase Price</b>
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
Entities affiliated with Newlight Partners LP	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.
- (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.

**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.

## [Table of Contents](#)

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:

<b>Stockholder</b>	<b>Shares of Series B Stock</b>	<b>Total Purchase Price</b>
Entities affiliated with Newlight Partners LP	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:

<b>Stockholder</b>	<b>Shares of Series C Stock</b>	<b>Total Purchase Price</b>
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 Newlight Partners LP(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



## [Table of Contents](#)

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 will terminate the Management Services Agreement in connection with this offering and pay Paragon a termination fee of \$2.6 million.

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 six months ended June 30, 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.

On August 31, 2018, we repurchased and canceled 1,623,007 shares of common stock from our former chief executive officer, Bob Repella, for \$3.2 million. Thereafter, we entered into litigation with Mr. Repella related to the value of his vested common stock. On October 24, 2019, in settlement of the litigation, we paid Mr. Repella an additional \$3.5 million for the shares.

In connection with this offering, our board of directors approved the grant of stock options pursuant to the 2020 Plan to certain employees of Paragon, including Jeffrey S. Aronin, the Chairman of our board of directors. The stock options cover an aggregate of 1,889,419 share of common stock, of which Mr. Aronin will receive 1,259,611 shares of common stock, and will become effective immediately following the determination of the initial public offering price per share of our common stock. Each option has a per share exercise price equal to that initial public offering price, and will vest as to one-fifth of the shares underlying the option on each of the first five anniversaries of the date on which this offering is consummated, subject to continued service through the applicable vesting date.

### ***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."

## [Table of Contents](#)

### *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.

### **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 Nasdaq Global Market. 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 July 31, 2020 (i) reflecting the automatic conversion of all outstanding shares of our convertible preferred stock into 38,771,766 shares of our common stock, (ii) the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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 38,771,766 shares of our common stock and the payment of an accrued dividend to holders of our convertible preferred stock in the aggregate amount of 11,751,763 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 58,329,377 total shares of our common stock outstanding, in each case, immediately following the conversion of all outstanding shares of our convertible preferred stock, inclusive of the accrued dividend, into 50,523,529 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.

## Table of Contents

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.

Name of beneficial owner	Shares beneficially owned prior to the offering				Assuming no exercise of option to purchase additional shares	Assuming exercise of option to purchase additional shares
	Common stock	Options exercisable within 60 days	Aggregate number of shares beneficially owned	%	%	%
<b>5% or more stockholders:</b>						
Valor IV Pharma Holdings, LLC(1)	13,166,357	—	13,166,357	22.6%	20.9%	20.7%
Entities affiliated with FMR LLC (Fidelity)(2)	8,052,110	—	8,052,110	13.8%	12.8%	12.6%
HBM Healthcare Investments (Cayman) Ltd.(3)	5,268,663	—	5,268,663	9.0%	8.4%	8.3%
Entities affiliated with Vivo Capital LLC(4)	5,063,017	—	5,063,017	8.7%	8.0%	8.0%
Marshman Fund Trust II(5)	10,958,547	—	10,958,547	18.8%	17.4%	17.2%
Novo Holdings A/S(6)	4,277,300	—	4,277,300	7.3%	6.8%	6.7%
Entities affiliated with Newlight Partners LP(7)	2,965,581	—	2,965,581	5.1%	4.7%	4.7%
venBio Global Strategic Fund II LP(8)	4,026,784	—	4,026,784	6.9%	6.4%	6.3%
<b>Named executive officers and directors:</b>						
John C. Jacobs	—	237,542	237,542	*	*	*
Jeffrey Dayno	—	42,604	42,604	*	*	*
Andrew Serafin	—	80,340	80,340	*	*	*
John Vittoria	—	—	—	—	—	—
Jeffrey S. Aronin	—	—	—	—	—	—
Martin Edwards(6)	4,277,300	—	4,277,300	7.3%	6.8%	6.7%
Antonio Gracias(1)	13,166,357	—	13,166,357	22.6%	20.9%	20.7%
Jack Bech Nielsen(4)	5,063,017	—	5,063,017	8.7%	8.0%	8.0%
Aaron Royston(8)	4,026,784	—	4,026,784	6.9%	6.4%	6.3%
Juan A. Sabater(1)	13,166,357	—	13,166,357	22.6%	20.9%	20.7%
Gary Sender	—	—	—	—	—	—
Andreas Wicki(3)	5,268,663	—	5,268,663	9.0%	8.4%	8.3%
All current directors and executive officers as a group (14 persons)	<b>44,968,478</b>	<b>394,569</b>	<b>45,363,047</b>	<b>77.2%</b>	<b>71.6%</b>	<b>70.8%</b>

\* Represents beneficial ownership of less than 1% of outstanding shares of our common stock.

- (1) 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-A L.P. and 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) 845,339 shares of common stock and (ii) 4,026,784 shares of common stock issuable upon the deemed conversion of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Valor IV

## Table of Contents

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) 2,035,053 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (ii) 1,373,151 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Growth Company Commingled Pool, (iii) 500,356 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, (iv) 781,042 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund, (v) 250,132 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Variable Insurance Products Fund IV: Health Care Portfolio, (vi) 2,009,956 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Select Portfolios: Health Care Portfolio, (vii) 964,994 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund, and (viii) 137,426 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, 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 5,268,663 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, 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) 4,448,705 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, held by Vivo Capital Fund VIII, L.P. and (ii) 614,312 shares of common stock issuable upon the deemed conversion of shares of preferred stock, and payment of the corresponding cumulative accrued dividend, 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) 6,931,763 shares of common stock and (ii) 4,026,784 shares of common stock issuable upon the deemed conversion of preferred stock, and payment of the corresponding cumulative accrued dividend, 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 4,277,300 shares of common stock issuable upon the deemed conversion of the convertible preferred stock, and payment of the corresponding cumulative accrued dividend, held

## Table of Contents

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 (i) 461 shares of common stock issuable upon the deemed conversion of the convertible preferred stock, and payment of the corresponding cumulative accrued dividend, held by SCI Partners LP and (ii) 2,965,120 shares of common stock issuable upon the deemed conversion of the convertible preferred stock, and payment of the corresponding cumulative accrued dividend, held by QSIP LP (the "Newlight Shares"). Pursuant to an investment management agreement, QSIP LP and certain of its affiliates have delegated sole voting and dispositive power over the Newlight 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. In such capacities, each of the entities and individuals referenced in this paragraph may also be deemed to be the beneficial owners having shared voting power and shared investment power with respect to the Newlight Shares as described above. The business address of Newlight Partners LP is 320 Park Avenue, 25<sup>th</sup> Floor, New York, NY 10022.
- (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 4,026,784 shares of common stock issuable upon the deemed conversion of the convertible preferred stock, and payment of the corresponding cumulative accrued dividend, 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:

- 500,000,000 shares of common stock, par value \$0.00001 per share; and
- 10,000,000 shares of preferred stock, par value \$0.00001 per share.

We are selling 4,651,163 shares of common stock in this offering (697,674 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 11,751,763 shares of our common stock and (iii) all outstanding shares of our redeemable preferred stock will automatically be cancelled.

## [Table of Contents](#)

Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 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

## [Table of Contents](#)

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, or the Exchange Act of 1934, 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 Computershare Trust Company, N.A.

## **Trading Symbol and Market**

We have applied to list our common stock on the Nasdaq Global Market 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 Global Market, 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 62,980,540 shares of common stock, assuming the issuance of 4,651,163 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

## [Table of Contents](#)

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 Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

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 58,273,144 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 SARs, and common stock



---

[Table of Contents](#)

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(l)(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

## [Table of Contents](#)

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

## [Table of Contents](#)

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.

<u>Underwriters</u>	<u>Number of Shares</u>
Goldman Sachs & Co. LLC	
Jefferies LLC	
Piper Sandler & Co.	
Total	<u>4,651,163</u>

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 697,674 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 697,674 additional shares from us.

	<u>No Exercise</u>	<u>Full Exercise</u>
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

## [Table of Contents](#)

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 Global Market 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 Global Market, 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 \$4.5 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$30,000.

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 “qualified 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,



## [Table of Contents](#)

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](http://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](http://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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
<b>Harmony Biosciences Holdings, Inc. and Subsidiary</b>	
<b>As of December 31, 2019 and 2018 and for the Year Ended December 31, 2019 and 2018</b>	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheet</a>	F-4
<a href="#">Consolidated Statement of Operations and Comprehensive Loss</a>	F-5
<a href="#">Consolidated Statement of Convertible Preferred Stock and Stockholders' Deficit</a>	F-6
<a href="#">Consolidated Statement of Cash Flows</a>	F-7
<a href="#">Notes to Consolidated Financial Statements</a>	F-8
	Page
<b>Harmony Biosciences Holdings, Inc. and Subsidiary</b>	
<b>As of June 30, 2020 and December 31, 2019 and for the Six Months Ended June 30, 2020 and 2019</b>	
<a href="#">Condensed Consolidated Balance Sheets (Unaudited)</a>	F-30
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)</a>	F-31
<a href="#">Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (Unaudited)</a>	F-32
<a href="#">Condensed Consolidated Statements of Cash Flows (Unaudited)</a>	F-33
<a href="#">Notes to Condensed Consolidated Financial Statements (Unaudited)</a>	F-34

## [Table of Contents](#)

*The accompanying financial statements give effect to a 1-for-8.215 reverse stock split of the common stock of Harmony Biosciences Holdings, Inc. which will take place prior to the effective date of the registration statement. The following report is in the form which will be furnished by Deloitte & Touche LLP, an independent registered public accounting firm, upon completion of the 1-for-8.215 reverse stock split of the common stock of Harmony Biosciences Holdings, Inc. described in Note 17 to the financial statements and, assuming that from April 10, 2020 to the date of such completion, no other material events have occurred that would affect the accompanying financial statements or disclosures therein.*

*/s/ Deloitte & Touche LLP*

*Chicago, Illinois  
August 11, 2020*

### **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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial

---

[Table of Contents](#)

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.

Chicago, Illinois

April 10, 2020 (August 31, 2020 as to the effect of the reverse stock split discussed at Note 17)

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
<b>ASSETS</b>		
CURRENT ASSETS:		
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
<b>TOTAL ASSETS</b>	<b>\$ 106,703</b>	<b>\$ 89,282</b>
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Trade payables	\$ 6,360	\$ 1,462
Accrued compensation	7,917	3,953
Accrued expenses	5,500	1,816
Other current liabilities	115	-
Total current liabilities	19,892	7,231
NONCURRENT LIABILITIES:		
Deferred rent	287	262
Long term debt, net	97,946	-
Other noncurrent liabilities	163	261
Total noncurrent liabilities	98,396	523
<b>TOTAL LIABILITIES</b>	<b>\$ 118,288</b>	<b>\$ 7,754</b>
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; 7,787,470 issued and outstanding at December 31, 2019; 398,030,000 shares authorized; 7,777,100 issued and outstanding at December 31, 2018	-	-
Accumulated deficit	(422,862)	(242,673)
<b>TOTAL STOCKHOLDERS' DEFICIT</b>	<b>(422,862)</b>	<b>(242,673)</b>
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 106,703</b>	<b>\$ 89,282</b>

*The accompanying notes are an integral part of the consolidated financial statements*

**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	-	-
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	\$ (24.07)	\$ (7.91)
Weighted average number of shares of common stock, basic and diluted	7,777,441	8,857,622
PRO FORMA LOSS PER SHARE:		
Pro forma net loss available to common stockholders (unaudited)	\$ (151,977)	
Pro forma loss per share, basic and diluted (unaudited)	\$ (3.09)	
Weighted average number of shares of common stock used in computing pro forma loss per share, basic and diluted (unaudited)	49,239,211	

*The accompanying notes are an integral part of the consolidated financial statements*

**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 Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Series A, B, & C		Shares (1)	Amount			
	Shares	Amount					
Balance as of December 31, 2017	270,000,000	\$266,750	9,400,107	\$ -	\$ -	\$ (168,019)	\$ (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	-	-	(1,623,007)	-	-	(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	7,777,100	\$ -	\$ -	\$ (242,673)	\$ (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	-	32,160	-	-	(9,994)	(22,166)	(32,160)
Preferred stock accretion, Series A	-	2,742	-	-	-	(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	-	-	10,370	-	85	-	85
Stock-based compensation	-	-	-	-	9,909	-	9,909
Balance as of December 31, 2019	<u>318,510,205</u>	<u>\$411,275</u>	<u>7,787,470</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ (422,862)</u>	<u>\$ (422,862)</u>

(1) Common stock of Harmony Bioscience Holdings, Inc.

*The accompanying notes are an integral part of the consolidated financial statements*

**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
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(151,977)	\$ (39,898)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	395	184
Intangible amortization	2,815	-
Milestones associated with acquired in-process research & development (IPR&D)	52,000	-
Stock-based compensation expense	9,909	1,079
Noncash paid-in-kind interest expense	2,538	-
Debt issuance costs amortization	592	-
<i>Change in operating assets and liabilities:</i>		
Trade receivables	(4,255)	-
Inventory	(1,088)	-
Prepaid expenses and other assets	1,467	(2,589)
Other non-current assets	(420)	(522)
Trade payables	4,898	(610)
Accrued expenses and other liabilities	7,763	3,033
Other non-current liabilities	(73)	524
Net cash used in operating activities	<u>(75,436)</u>	<u>(38,799)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
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	<u>(127,149)</u>	<u>(1,342)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of preferred stock	50,000	25,000
Preferred stock issuance costs	(1,132)	(185)
Repurchase of common stock	-	(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	<u>143,769</u>	<u>21,615</u>
NET DECREASE IN CASH	<u>(58,816)</u>	<u>(18,526)</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	84,023	102,549
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	<u>\$ 25,207</u>	<u>\$ 84,023</u>
<i>Supplemental Disclosure of Cash Flow Information:</i>		
Cash paid during the year for interest	\$ 4,230	\$ -
Cash paid during the year for milestones	127,000	-
<i>Supplemental Disclosures of Noncash Investing and Financing Activities:</i>		
Series A Preferred Stock accrued return	\$ 32,160	\$ 29,207
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	-

*The accompanying notes are an integral part of the consolidated financial statements*

**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 \$422,862 and \$242,673, 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<sup>®</sup>, 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<sup>®</sup>. 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

## [Table of Contents](#)

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 December 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	<u>\$25,207</u>	<u>\$84,023</u>

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.

## [Table of Contents](#)

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).

### **Unaudited Pro Forma Information**

Immediately prior to the completion of the Company's IPO, all outstanding shares of redeemable convertible preferred stock will automatically convert into common stock. Unaudited pro forma balance sheet information as of December 31, 2019, assumes the conversion of all outstanding redeemable

convertible preferred stock into shares of common stock. The shares of common stock issuable and the proceeds expected to be received in the IPO are excluded from such pro forma financial information. The unaudited pro forma net income per share for the year ended December 31, 2019, was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of redeemable convertible preferred stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later. The unaudited pro forma net income per share does not include the shares expected to be sold and related proceeds to be received from the IPO.

### ***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, and has updated such evaluation for disclosure purposes through August , 2020 with respect to the reverse stock split reflected in the amendment to the Company's amended and restated certificate of incorporation, filed August , 2020, as discussed below. 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).

### **Reverse Stock Split**

On August , 2020, the Company implemented a 1-for-8.215 reverse stock split of the Company's common stock. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's Preferred Stock were proportionately reduced and the respective conversion prices were proportionately increased. As of December 31, 2018 and 2019, all outstanding shares of preferred stock were convertible into shares of common stock on a 1-for-8.215 basis.

### **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

## [Table of Contents](#)

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 guidance 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

## [Table of Contents](#)

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 December 31,	
	2019	2018
Raw materials	\$ 384	\$ -
Work in process	417	-
Finished goods	287	-
Total inventory, net	<u>\$1,088</u>	<u>\$ -</u>

### **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:

	As of December 31,	
	2019	2018
Gross Carrying Amount	\$75,000	\$ -
Accumulated Amortization	(2,815)	-
Net Book Value	<u>\$72,185</u>	<u>\$ -</u>

### **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

## [Table of Contents](#)

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
	<u>\$5,500</u>	<u>\$1,816</u>

### 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.



## [Table of Contents](#)

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:

<b>Years ending December 31,</b>	
2020	\$ 726
2021	443
2022	443
2023	443
2024	148
Thereafter	-
<b>Total</b>	<b><u>\$2,203</u></b>

### **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

## [Table of Contents](#)

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 sheet.

### ***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 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 \$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 7,709,434 of outstanding common units were converted to 7,709,434 of common shares.

On September 22, 2017, the Company issued 1,690,672 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 1,690,672 common shares and proceeds of \$139.

On August 31, 2018, the Company repurchased and canceled 1,623,007 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 7,787,470 and 7,777,100 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.

1,217,285 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 Ended December 31,	
	2019	2018
Wakix®	\$5,995	\$ -
Total	<u>5,995</u>	<u>-</u>

**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	1,992,037	\$ 8.22	9.07
Stock options issued	458,917	\$ 8.22	
Stock exercised	(10,370)	\$ 8.22	
Stock options forfeited	(65,366)	\$ 8.22	
Awards outstanding—December 31, 2019	<u>2,375,218</u>	\$ 8.22	8.33

As of December 31, 2019 and 2018, 573,098 and 186,870, 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

## [Table of Contents](#)

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.

	<u>2019</u>	<u>2018</u>
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 \$3.45 and \$3.29 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:

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
Research and development expense	\$ 287	\$ 209
Sales and marketing expense	351	415
General and administrative expense	9,271	455
	<u>\$9,909</u>	<u>\$1,079</u>

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.

	<u>Stock Compensation Expense</u>
<u>Years Ending December 31,</u>	
2020	\$ 1,627
2021	1,627
2022	1,493
2023	554
2024	148

[Table of Contents](#)

**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
	<u>\$ -</u>	<u>\$ -</u>
Current	\$ -	\$ -
Deferred	(42,149)	(12,151)
Valuation allowance	42,149	12,151
Total	<u>\$ -</u>	<u>\$ -</u>

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	<u>-%</u>	<u>-%</u>

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,			
	2019		2018	
	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	<u>\$ 100,823</u>	<u>167</u>	<u>58,621</u>	<u>114</u>
Net deferred tax asset	\$ 100,656	\$ -	58,507	\$ -
Valuation allowance	\$(100,656)	\$ -	(58,507)	\$ -
Total	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

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 is 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



## [Table of Contents](#)

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,	
	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	7,777,441	8,857,622
Net loss per share attributed to common stockholders, basic and diluted	\$ (24.07)	\$ (7.91)

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 December 31,	
	2019	2018
Stock options to purchase common stock	2,271,632	1,682,934
Convertible preferred stock	36,891,576	35,605,099
Total	39,163,208	37,288,033

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net income per share attributable to common stockholders (in thousands, except share and per share data) assuming the automatic conversion of the redeemable convertible preferred stock upon consummation of an IPO as if such event had occurred as of the beginning of the respective period:

	Year Ended
	December 31, 2019
Numerator	
Net Loss	\$ (151,977)
Pro forma net loss available to common shareholders	\$ (151,977)
Denominator	
Pro forma weighted-average common share outstanding basic and diluted	49,239,211
Pro forma net loss per share attributed to common stockholders, basic and diluted	\$ (3.09)

## **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.

### ***Reverse Stock Split***

On August 1, 2020, the Company implemented a 1-for-8.215 reverse stock split of the Company's common stock. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's Preferred Stock were proportionately reduced and the respective conversion prices were proportionately increased. As of December 31, 2018 and 2019, all outstanding shares of preferred stock were convertible into shares of common stock on a 1-for-8.215 basis.

**HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY**  
**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands except share and per share data)

	June 30, 2020	December 31, 2019	Pro Forma June 30, 2020
<b>ASSETS</b>			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 76,280	\$ 24,457	\$ 76,280
Trade receivables, net	15,239	4,255	15,239
Inventory, net	2,083	1,088	2,083
Prepaid expenses	4,669	1,436	4,669
Other current assets	16	261	16
Total current assets	<u>98,287</u>	<u>31,497</u>	<u>98,287</u>
NONCURRENT ASSETS:			
Property and equipment, net	1,138	1,330	1,138
Restricted cash	750	750	750
Intangible asset, net	68,492	72,185	68,492
Other noncurrent assets	152	941	152
Total noncurrent assets	<u>70,532</u>	<u>75,206</u>	<u>70,532</u>
<b>TOTAL ASSETS</b>	<b><u>\$ 168,819</u></b>	<b><u>\$ 106,703</u></b>	<b><u>\$ 168,819</u></b>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT</b>			
CURRENT LIABILITIES:			
Trade payables	\$ 2,073	\$ 6,360	\$ 2,073
Accrued compensation	4,021	7,917	4,021
Accrued expenses	14,967	5,500	14,967
Other current liabilities	-	115	-
Total current liabilities	<u>21,061</u>	<u>19,892</u>	<u>21,061</u>
NONCURRENT LIABILITIES:			
Deferred rent	322	287	322
Warrant liability	3,943	-	3,943
Long term debt, net	192,518	97,946	192,518
Other noncurrent liabilities	326	163	326
Total noncurrent liabilities	<u>197,109</u>	<u>98,396</u>	<u>197,109</u>
<b>TOTAL LIABILITIES</b>	<b><u>218,170</u></b>	<b><u>118,288</u></b>	<b><u>218,170</u></b>
<b>COMMITMENTS AND CONTINGENCIES (Note 9)</b>			
<b>CONVERTIBLE PREFERRED STOCK</b>			
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 June 30, 2020 and December 31, 2019; no shares issued and outstanding pro forma	367,442	348,203	-
Series B convertible preferred stock—\$1.25 stated value; 8,030,000 shares authorized; 8,000,000 issued and outstanding at June 30, 2020 and December 31, 2019; no shares issued and outstanding pro forma	12,639	12,023	-
Series C convertible preferred stock—\$1.96 stated value; 29,000,000 shares authorized; 25,510,000 issued and outstanding at June 30, 2020; 25,600,000 shares authorized; 25,510,000 issued and outstanding at December 31, 2019; no shares issued and outstanding pro forma	53,930	51,051	-
<b>STOCKHOLDERS' DEFICIT:</b>			
Common stock—\$0.00001 par value; 424,000,000 shares authorized; 7,805,848 issued and outstanding at June 30, 2020; 423,630,000 shares authorized; 7,787,470 issued and outstanding at December 31, 2019; 57,652,956 shares issued and outstanding, pro forma	-	-	1
Additional paid in capital	-	-	434,011
Accumulated deficit	<u>(483,362)</u>	<u>(422,862)</u>	<u>(483,363)</u>
<b>TOTAL STOCKHOLDERS' DEFICIT</b>	<b><u>(483,362)</u></b>	<b><u>(422,862)</u></b>	<b><u>(49,351)</u></b>
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT</b>	<b><u>\$ 168,819</u></b>	<b><u>\$ 106,703</u></b>	<b><u>\$ 168,819</u></b>

*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 share and per share data)**

	Six Months Ended June 30,	
	2020	2019
Net product revenues	\$ 57,845	\$ -
Cost of product sold	9,930	-
Gross profit	47,915	-
Operating expenses:		
Research and development	7,600	57,983
Sales and marketing	25,697	14,569
General and administrative	15,772	9,854
Total operating expenses	49,069	82,406
Operating loss	(1,154)	(82,406)
Loss on debt extinguishment	(22,639)	-
Other income (expense), net	(1,546)	-
Interest income (expense), net	(13,308)	(1,231)
Loss before income taxes	(38,647)	(83,637)
Income taxes	-	-
Net loss and comprehensive loss	\$ (38,647)	\$ (83,637)
Accumulation of yield on preferred stock	(20,891)	(16,629)
Net loss available to common stockholders	\$ (59,538)	\$ (100,266)
LOSS PER SHARE:		
Loss per share, basic and diluted	\$ (7.63)	\$ (12.89)
Weighted average number of shares of common stock, basic and diluted	7,798,928	7,777,100
PRO FORMA LOSS PER SHARE:		
Pro forma net loss available to common stockholders (unaudited)	\$ (38,647)	
Pro forma loss per share, basic and diluted (unaudited)	\$ (0.70)	
Weighted average number of shares of common stock used in computing pro forma loss per share, basic and diluted (unaudited)	55,278,574	

*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 except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Series A, B, & C						
	Shares	Amount	Shares (1)	Amount			
Balance as of December 31, 2019	318,510,205	\$411,275	7,787,470	\$ -	\$ -	\$ (422,862)	\$ (422,862)
Net loss	-	-	-	-	-	(38,647)	(38,647)
Preferred stock dividend, Series A	-	17,688	-	-	(1,048)	(16,640)	(17,688)
Preferred stock accretion, Series A	-	1,551	-	-	-	(1,551)	(1,551)
Preferred stock dividend, Series B	-	604	-	-	-	(604)	(604)
Preferred stock accretion, Series B	-	12	-	-	-	(12)	(12)
Preferred stock dividend, Series C	-	2,599	-	-	-	(2,599)	(2,599)
Preferred stock accretion, Series C	-	280	-	-	-	(280)	(280)
Exercise of Options	-	-	30,553	-	251	-	251
Stock-based compensation	-	-	-	-	797	-	797
Repurchase and cancellation of common units	-	-	(12,175)	-	-	(167)	(167)
Balance as of June 30, 2020	<u>318,510,205</u>	<u>\$434,009</u>	<u>7,805,848</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ (483,362)</u>	<u>\$ (483,362)</u>

	Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Series A & B						
	Shares	Amount	Shares (1)	Amount			
Balance as of December 31, 2018	293,000,000	\$324,201	7,777,100	\$ -	\$ -	\$ (242,673)	\$ (242,673)
Net loss	-	-	-	-	-	(83,637)	(83,637)
Preferred stock dividend, Series A	-	16,080	-	-	(696)	(15,384)	(16,080)
Preferred stock accretion, Series A	-	1,372	-	-	-	(1,372)	(1,372)
Preferred stock dividend, Series B	-	549	-	-	-	(549)	(549)
Preferred stock accretion, Series B	-	11	-	-	-	(11)	(11)
Stock-based compensation	-	-	-	-	696	-	696
Balance as of June 30, 2019	<u>293,000,000</u>	<u>\$342,213</u>	<u>7,777,100</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ (343,626)</u>	<u>\$ (343,626)</u>

(1) Common stock of Harmony Bioscience Holdings, Inc.

*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 CASH FLOWS**  
(In thousands except share and per share data)

	Six Months Ended June 30,	
	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (38,647)	\$(83,637)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	194	212
Intangible amortization	3,693	-
Milestones associated with acquired in-process research & development (IPR&D)	-	50,000
Stock-based compensation expense	797	696
Stock appreciation rights market adjustment	139	-
Warrant expense	1,584	-
Noncash paid-in-kind interest expense	-	623
Debt issuance costs amortization	680	198
Loss on debt extinguishment	22,639	-
<i>Change in operating assets and liabilities:</i>		
Trade receivables	(10,984)	-
Inventory	(995)	-
Prepaid expenses and other assets	(2,987)	837
Other non-current assets	789	312
Trade payables	(4,287)	2,451
Accrued expenses and other current liabilities	5,456	215
Other non-current liabilities	59	97
Net cash used in operating activities	<u>(21,870)</u>	<u>(27,996)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(2)	(83)
Milestone associated with acquired in-process research & development (IPR&D)	-	(50,000)
Net cash used in investing activities	<u>(2)</u>	<u>(50,083)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from long term debt	200,000	75,000
Debt issuance costs	(5,804)	(4,309)
Extinguishment of debt	(102,538)	-
Extinguishment of debt exit fees	(18,047)	-
Proceeds from exercised options	251	-
Repurchase of common stock	(167)	-
Net cash provided by financing activities	<u>73,695</u>	<u>70,691</u>
<b>NET INCREASE/(DECREASE) IN CASH</b>	<u>51,823</u>	<u>(7,388)</u>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period</b>	<u>25,207</u>	<u>84,023</u>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period</b>	<u>\$ 77,030</u>	<u>\$ 76,635</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid during the year for interest	\$ 12,698	\$ 108
Cash paid during the year for milestones	-	50,000
<b>Supplemental Disclosures of Noncash Investing and Financing Activities:</b>		
Series A Preferred Stock accrued return	17,688	16,080
Series A accretion of issuance costs	1,551	1,372
Series B Preferred Stock accrued return	604	549
Series B accretion of issuance costs	12	11
Series C Preferred Stock accrued return	2,599	-
Series C accretion of issuance costs	280	-
Warrant financing	2,359	-

*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 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"). We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

**2. GOING CONCERN**

The unaudited 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 June 30, 2020, and December 31, 2019, the Company has an accumulated deficit of \$483,362 and \$422,862, 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 unaudited condensed consolidated financial statements are issued. The unaudited condensed 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 June 30, 2020, condensed consolidated statements of cash flows for the six months ended June 30, 2020 and 2019, and consolidated statements of

operations and comprehensive loss and the condensed consolidated statements of convertible preferred stock and shareholders' deficit for the six months ended June 30, 2020 and 2019, 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 statements of the Company's financial position as of June 30, 2020, and the results of its operations and its cash flows for the six months ended June 30, 2019 and 2020.

#### ***Fair Value of Financial Instruments***

The Company's unaudited condensed 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 unaudited condensed 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 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.



### **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 statements of cash flows.

	As of	
	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$76,280	\$ 24,457
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	<u>\$77,030</u>	<u>\$ 25,207</u>

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 June 30, 2020, three customers accounted for 100% of gross accounts receivable, Caremark LLC ("CVS Caremark"), which accounted for 43% of gross accounts receivable; PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 31% of gross accounts receivable; and Accredo Health Group, Inc ("Accredo"), which accounted for 26% of gross accounts receivable. For the six months ended June 30, 2020, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 42% of gross product revenues; Pantherx accounted for 33% of gross product revenues; and Accredo accounted for 25% 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.

### **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,

## [Table of Contents](#)

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 six months ended June 30, 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 unaudited condensed consolidated statements of operations and comprehensive loss is amortization of acquired developed technology of \$3,693 for the six months ended June 30, 2020.

### **Advertising Expenses**

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expense was \$5,779 in the six months ended June 30, 2020 and \$430 for the six months ended June 30, 2019.

### **Unaudited Pro Forma Information**

Immediately prior to the completion of the Company's IPO, all outstanding shares of redeemable convertible preferred stock will automatically convert into common stock. Unaudited pro forma balance sheet information as of June 30, 2020, assumes the conversion of all outstanding redeemable convertible preferred stock into shares of common stock. The shares of common stock issuable and the proceeds expected to be received in the IPO are excluded from such pro forma financial information.

The unaudited pro forma net income per share for the six months ended June 30, 2020, was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of redeemable convertible preferred stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later. The unaudited pro forma net income per share does not include the shares expected to be sold and related proceeds to be received from the IPO. Net income attributable to common stockholders used in the unaudited pro forma net income per share calculation was adjusted for the accretion of redeemable convertible preferred stock, as all preferred stock is not considered outstanding prior to the closing of the IPO.

## **4. INVENTORY**

Inventory, net consisted of the following:

	As of	
	June 30, 2020	December 31, 2019
Raw materials	\$ 414	\$ 384
Work in process	1,084	417
Finished goods	585	287
Total inventory, net	<u>\$ 2,083</u>	<u>\$ 1,088</u>

## **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

## [Table of Contents](#)

intangible asset, and, as of June, 2020 the remaining useful life was 9.25 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.

The gross carrying amount and net book value of the intangible asset is as follows:

	As of	
	June 30, 2020	December 31, 2019
Gross Carrying Amount	\$75,000	\$ 75,000
Accumulated Amortization	(6,508)	(2,815)
Net Book Value	<u>\$68,492</u>	<u>\$ 72,185</u>

## 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 six months ended June 30, 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 six months ended June 30, 2020, the Company has incurred \$9,277 for sales-based, trademark and tiered royalties recognized as cost of product sold. As of June 30, 2020 and December 31, 2019, the Company had accrued \$6,080 and \$938, respectively, for sales-based, trademark and tiered royalties.

## 7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	June 30, 2020	December 31, 2019
Royalties due to third parties	\$ 6,080	\$ 938
Rebates and other sales deductions	3,797	713
Research and development	2,016	894
Selling and marketing	1,542	1,547
Professional fees, consulting, and other services	1,419	510
Debt issuance costs	—	638
Employee travel and other expenses	113	260
	<u>\$14,967</u>	<u>\$ 5,500</u>

## 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 unaudited condensed 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. Borrowings under the OrbiMed Loan are collateralized by all of the Company's assets, excluding the intellectual property licensed through the License Agreement. 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 unaudited condensed consolidated statements 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 June 30, 2020 are \$5,320 and are presented in the unaudited condensed 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 410,239 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 \$3,943 at June 30, 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 unaudited condensed consolidated balance sheet at June 30, 2020. The portion of the OrbiMed Loan proceeds allocated to the warrant liability resulted in a debt discount, which is presented in the unaudited condensed 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 June 30, 2020 is \$2,162 and is presented in the unaudited condensed consolidated balance sheets as a direct deduction from the carrying value of the

## [Table of Contents](#)

debt. During the six months ended June 30, 2020, a loss of \$1,584 was recorded in other expense in the unaudited condensed consolidated statements of operations due to the change in the fair value of the warrant liability.

Interest paid for all outstanding debt totaled \$12,698 during the six months ended June 30, 2020, compared to \$108 for the six months ended June 30, 2019.

### **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 \$355 for the six months ended June 30, 2020, compared to \$297 for the six months ended June 30, 2019. The following table sets forth the lease payment obligations as of June 30, 2020, for the periods indicated below:

<b>Years ending December 31,</b>	
2020	\$ 363
2021	443
2022	443
2023	443
2024	184
Thereafter	-
<b>Total</b>	<b><u>\$1,876</u></b>

### **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,

## [Table of Contents](#)

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 June 30, 2020, and December 31, 2019, there were 286,000 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 is calculated on the original issue price and was \$86,452 and \$68,764 at June 30, 2020 and December 31, 2019, respectively. For the six months ended June 30, 2020 and 2019 accretion of issuance costs of \$1,551 and \$1,372, respectively, were recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$4,011 and \$6,934, respectively, are recorded as a direct reduction of Series A convertible preferred stock in the Company's unaudited condensed consolidated balance sheet.

### ***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 June 30, 2020 and December 31, 2019, 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 is calculated on original issue price and was \$2,680 and \$2,076 at June 30, 2020 and December 31, 2019, respectively. For the six months ended June 30, 2020 and 2019 accretion of issuance costs of \$12 and \$11, respectively, were recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$41 and \$64, respectively, are recorded as a direct reduction of Series B convertible preferred stock in the Company's unaudited condensed 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 June 30, 2020 and December 31, 2019, there were 29,000,000 and 25,600,000 shares, respectively, 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 is calculated on original issue price and was \$4,571 and \$1,973 at June 30, 2020 and December 31, 2019, respectively. For the six months ended June 30, 2020, accretion of issuance costs of \$280 were recorded as a direct charge to retained earnings, while issuance costs not yet accreted of \$642 are recorded as a direct reduction of Series C convertible preferred stock in the Company's unaudited condensed 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

## [Table of Contents](#)

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 June 30, 2020 and December 31, 2019.

### ***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 7,709,434 outstanding common units of Harmony Biosciences II, LLC, were converted to 7,709,434 common shares of Harmony Biosciences II, Inc.

On September 22, 2017, the Company issued warrants for 1,690,672 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 1,690,672 common shares and proceeds of \$139.

On August 31, 2018, the Company repurchased and canceled 1,623,007 common shares from the former chief executive officer for \$3,200.

As of June 30, 2020, there were 424,000,000 common shares authorized, of which 7,805,848, were issued and outstanding. As of December 31, 2019, there were 423,630,000 common shares authorized, of which and 7,787,470 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.

1,217,285 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 unaudited condensed 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 June 30, 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	2,375,218	\$ 8.22	8.33
Awards issued	186,657	\$ 9.12	
Awards exercised	(30,553)	\$ 8.22	
Awards forfeited	(69,251)	\$ 8.22	
Awards outstanding—June 30, 2020	<u>2,462,071</u>	\$ 8.30	7.95

As of June 30, 2020 and December 31, 2019, stock awards issued under the Plan for 709,524 and 573,098 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 six months ended June 30, 2020, the Company reversed \$10 out of stock-based compensation previously recorded, compared to \$4 for the six months ended June 30, 2019.

### 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.

## [Table of Contents](#)

The assumptions used to value the awards are summarized in the following table.

	As of	
	June 30, 2020	December 31, 2019
Dividend yield	0.00%	0.00%
Expected volatility	83.90 - 95.80%	95.30 - 99.30%
Risk-free interest rate	0.49 - 0.51%	1.60 - 2.59%
Lack of marketability discount	17.37 - 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 \$3.78 and \$3.45 in 2020 and 2019, respectively.

Stock-based compensation expense was \$936 for the six months ended June 30, 2020, compared to \$696 for the six months ended June 30, 2019, and was recorded in the unaudited condensed consolidated statements of operations and comprehensive loss in the following line items:

	Six Months Ended June 30,	
	2020	2019
Research and development expense	\$ 169	\$ 133
Sales and marketing expense	219	129
General and administrative expense	548	434
	<u>\$ 936</u>	<u>\$ 696</u>

Options issued under the Plan are reflected as a component of equity in these unaudited condensed consolidated financial statements. Stock appreciation rights are reflected as other non-current liability. The Company will recognize compensation expense for these awards as summarized in the following table.

Years Ending December 31,	Stock Compensation Expense
2020	\$ 1,882
2021	1,879
2022	1,748
2023	848
2024	386
2025	57

### **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.

## [Table of Contents](#)

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 six months ended June 30, 2020 and 2019, and the basic and diluted net loss per share attributable to common stockholders are the same for each six 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.

The following table sets forth the computation of basic and diluted net loss per share:

	Six Months Ended June 30,	
	2020	2019
<b>Numerator</b>		
Net Loss	\$ (38,647)	\$ (83,637)
Accumulation of yield on preferred stock	(20,891)	(16,629)
Net loss available to common shareholders	\$ (59,538)	\$ (100,266)
<b>Denominator</b>		
Weighted-average common share outstanding basic and diluted	7,798,928	7,777,100
Net loss per share attributed to common stockholders, basic and diluted	\$ (7.63)	\$ (12.89)

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:

	Six Months Ended June 30,	
	2020	2019
Stock options to purchase common stock	2,443,498	2,139,299
Convertible preferred stock	39,161,737	35,666,464
<b>Total</b>	<b>41,605,235</b>	<b>37,805,763</b>

## [Table of Contents](#)

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net income per share attributable to common stockholders (in thousands, except share and per share data) assuming the automatic conversion of the redeemable convertible preferred stock upon consummation of an IPO as if such event had occurred as of the beginning of the respective period:

	<u>Year Ended June 30, 2020</u>
Numerator	
Net Loss	\$ (38,647)
Pro forma net loss available to common shareholders	\$ (38,647)
Denominator	
Pro forma weighted-average common share outstanding basic and diluted	55,278,574
Pro forma net loss per share attributed to common stockholders, basic and diluted	\$ (0.70)

### **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 six months ended June 30, 2020. The Company's financial assets and liabilities which are measured at fair value on a recurring basis were comprised of cash, cash equivalents, and restricted cash of \$77,030 and \$25,207 at June 30, 2020 and December 31, 2019, respectively, based on Level 1 inputs, and a warrant liability of \$3,943 and \$0 at June 30, 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 unaudited condensed consolidated balance sheets at June 30, 2020. Any subsequent changes in the fair value of the warrant liability will be recorded in current period earnings as other expense/income. During the six months ended June 30, 2020, a loss of \$1,584 was recorded in other expense in the unaudited condensed consolidated statements of operations due to the change in the fair value of the warrant liability.

The assumptions used to determine the fair value of the warrant liability as of June 30, 2020 were as follows:

Dividend yield	0.00%
Expected volatility	58.2%
Risk-free interest rate	0.17%
Lack of marketability discount	0.00%
Dividend yield	0.00%
Expected term (years)	1.0

### **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 six months ended June 30, 2020, the Company incurred \$3,474 in management fee expense and other expenses to this related party, which are included in general and administrative expense in the unaudited condensed consolidated statements of operations and comprehensive loss as compared to

## [Table of Contents](#)

\$2,619 for the six months ended June 30, 2019. 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 June 30, 2020, and December 31, 2019, the amount due to related parties included in current liabilities was \$230 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 the Company or its 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 the Company’s 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 the Company’s clinical trials; impair the Company’s ability to meet demand for new WAKIX® prescriptions; impede the Company’s clinical trial recruitment, testing, monitoring, data collection and analysis and other related activities; and have a material impact on the Company’s 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 the Company’s 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 and, as necessary, made changes to these unaudited condensed consolidated financial statements for subsequent events through August 5, 2020, the date these unaudited condensed consolidated financial statements were available to be issued, and has updated such evaluation for disclosure purposes through August 1, 2020 with respect to the reverse stock split reflected in the amendment to the Company’s amended and restated certificate of incorporation, filed August 1, 2020, as discussed below. All subsequent events that provided additional evidence about conditions existing at the date of the unaudited condensed consolidated statements of financial position were incorporated into the unaudited condensed consolidated financial statements.

#### ***Reverse Stock Split***

On August 1, 2020, the Company implemented a 1-for-8.215 reverse stock split of the Company’s common stock. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company’s Preferred Stock were proportionately reduced and the respective conversion prices were proportionately increased. As of June 30, 2020 and 2019, all outstanding shares of preferred stock were convertible into shares of common stock on a 1-for-8.215 basis.

4,651,163 Shares



Common Stock

**Goldman Sachs & Co. LLC**

**Jefferies**

**Piper Sandler**

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.

	Amount to be paid
SEC registration fee	\$ 15,968.42
FINRA filing fee	18,953.49
Exchange listing fee	25,000
Accounting fees and expenses	1,250,000
Legal fees and expenses	2,500,000
Printing expenses	625,000
Transfer agent and registrar fees	3,500
Miscellaneous expenses	50,000
<b>Total</b>	<b>\$ 4,488,421.91</b>

**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.

## Table of Contents

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 34,692,635 shares of our Series A convertible preferred stock, or Series A stock, at a purchase price of \$8.22 per share for aggregate consideration of approximately \$285.0 million.

On January 8, 2018, we issued and sold an aggregate of 973,828 shares of our Series B convertible preferred stock, or Series B stock, at a purchase price of \$10.27 per share for aggregate consideration of approximately \$10.0 million.

On August 9, 2019, we issued and sold an aggregate of 3,105,320 shares of our Series C convertible preferred stock at a purchase price of \$16.10 per share, for aggregate consideration of approximately \$50.0 million.

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 June 30, 2020, we granted to our employees, directors, consultants and certain employees and affiliates of Paragon options to purchase up to 2,636,988 shares and 21,301 shares of common stock under our Equity Incentive Plan, at exercise prices of \$8.22 per share and \$13.72 per share, respectively. 204,601 of these options were terminated, expired without being exercised or were otherwise forfeited.

As of June 30, 2020, we have issued an aggregate of 40,922 shares of common stock pursuant to the exercise of stock options by employees and affiliates of Paragon. Of these issuances, 12,173 shares of common stock have been repurchased and canceled. 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 June 30, 2020, we granted stock appreciation rights to certain employees and affiliates of Paragon for up to 46,251 shares and 9,129 shares of common stock under our Equity Incentive Plan, at base prices of \$8.22 per share and \$13.72 per share, respectively. Of the stock appreciation rights granted through June 30, 2020, stock appreciation rights for 6,086 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

## Table of Contents

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 410,239 shares of our Series C convertible preferred stock at a price of \$16.10 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	<a href="#">Third Amendment to Third Amended and Restated Certificate of Incorporation of the Registrant, in effect prior to the consummation of this offering.</a>
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	<a href="#">Opinion of Latham &amp; Watkins LLP.</a>
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*	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.
10.3†	<a href="#">Harmony Biosciences Holdings, Inc. Amended and Restated Equity Incentive Plan and form of option agreement.</a>

## Table of Contents

### Exhibit No.

10.4†	<a href="#">2020 Incentive Award Plan.</a>
10.5†	<a href="#">Form of Option Agreement pursuant to 2020 Incentive Award Plan</a>
10.6†	<a href="#">Form of Restricted Stock Unit Agreement pursuant to 2020 Incentive Award Plan</a>
10.7†	<a href="#">2020 Employee Stock Purchase Plan</a>
10.8†	<a href="#">Amended and Restated Employment Agreement, dated August 11, 2020, by and between Harmony Biosciences, LLC and John C. Jacobs.</a>
10.9†	<a href="#">Offer Letter, dated October 10, 2017, by and between Harmony Biosciences, LLC and Jeffrey Dayno.</a>
10.10†	<a href="#">Offer Letter, dated September 8, 2017, by and between Harmony Biosciences, LLC and Andrew Serafin.</a>
10.11†	<a href="#">Offer Letter, dated September 29, 2018, by and between Harmony Biosciences, LLC and John Vittoria.</a>
10.12	<a href="#">Form of Indemnification Agreement between Harmony Biosciences, LLC and each director and executive officer.</a>
10.13†	<a href="#">Harmony Biosciences, LLC Separation Plan</a>
10.14#*	License and Commercialization Agreement, dated July 28, 2017, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.
10.15*	Amendment No. 1 to License and Commercialization Agreement, dated August 27, 2018, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.
10.16#*	Trademark License Agreement, dated August 23, 2018, by and among Bioprojet Europe, Ltd., Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.
10.17*	Management Services Agreement, dated September 22, 2017, by and between Paragon Biosciences, LLC and Harmony Biosciences, LLC.
10.18*	Right of Use Agreement, dated November 1, 2019, by and between Paragon Biosciences, LLC and Harmony Biosciences, LLC.
10.19*	Second Amended and Restated Investors' Rights Agreement, dated August 9, 2019, by and among the Registrant and the other parties thereto.
21.1*	<a href="#">List of Subsidiaries of the Registrant.</a>
23.1	<a href="#">Consent of Deloitte &amp; Touche LLP, independent registered public accounting firm.</a>
23.2	<a href="#">Consent of Latham &amp; Watkins LLP (included in Exhibit 5.1).</a>
24.1*	<a href="#">Power of Attorney (included on signature page).</a>

\* Previously filed.

† 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.

\*\*\*

### **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.

## [Table of Contents](#)

(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 August 11, 2020.

HARMONY BIOSCIENCES HOLDINGS, INC.

By: /s/ John C. Jacobs  
Name: John C. Jacobs  
Title: President, Chief Executive Officer and Director

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>	<u>Date</u>
<u>/s/ John C. Jacobs</u> John C. Jacobs	President, Chief Executive Officer and Director (Principal Executive Officer)	August 11, 2020
<u>/s/ Susan L. Drexler</u> Susan L. Drexler	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 11, 2020
<u>*</u> Jeffrey S. Aronin	Chairman of the Board	August 11, 2020
<u>*</u> Martin Edwards	Director	August 11, 2020
<u>*</u> Antonio Gracias	Director	August 11, 2020

[Table of Contents](#)

<u>Signature</u>	<u>Title</u>	<u>Date</u>
* _____ Jack Bech Nielsen	Director	August 11, 2020
* _____ Aaron Royston	Director	August 11, 2020
* _____ Juan A. Sabater	Director	August 11, 2020
* _____ Gary Sender	Director	August 11, 2020
* _____ Dr. Andreas Wicki	Director	August 11, 2020
*By: /s/ John C. Jacobs _____ John C. Jacobs Attorney-in-Fact		

**CERTIFICATE OF AMENDMENT  
OF  
THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF  
HARMONY BIOSCIENCES HOLDINGS, INC.**

Harmony Biosciences Holdings, Inc. (the “**Corporation**”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware, as the same exists or may hereafter be amended (the “**DGCL**”), does hereby 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 (i) the holders of a majority in voting power of the issued and outstanding shares of Series A Preferred Stock, par value \$0.00001 per share, of the Corporation, Series B Preferred Stock, par value \$0.00001 per share, of the Corporation and Series C Preferred Stock, par value \$0.00001 per share, of the Corporation (collectively, the “**Preferred Stock**”), voting together as a single class and on an as-converted to Common Stock (as defined below) basis, and (ii) the holders of a majority in voting power of the outstanding shares of (x) common stock, par value \$0.00001 per share (“**Common Stock**”), of the Corporation and (y) Preferred Stock on an as-converted to Common Stock basis, voting together as a single class.

**THIRD:** Immediately upon the effectiveness of the Amendment and without further action by the Corporation or any holders thereof, Article Fourth of the Third Amended and Restated Certificate of Incorporation of the Corporation, as amended, shall be amended and restated in its entirety to read as follows:

The Corporation is authorized to issue two classes of stock to be designated, respectively, “Common Stock” and “Preferred Stock.” The total number of shares which the Corporation is authorized to issue is currently 1,100,000,000 shares, of which (i) 600,000,000 shares shall be Common Stock (the “**Common Stock**”), and (ii) 500,000,000 shares shall be Preferred Stock (the “**Preferred Stock**”). The Preferred Stock shall have a par value of \$0.00001 per share. The Common Stock shall have a par value of \$0.00001 per share.

Effective upon the filing of this Certificate of Amendment with the Secretary of State of the State of Delaware (the “**Stock Split Effective Time**”), each eight and two hundred fifteen thousandths (8.215) shares of Common Stock outstanding or held in treasury immediately prior to such time shall automatically and without any action on the part of the Corporation or the holders thereof be reclassified into one (1) share of Common Stock (the “**Reverse Stock Split**”). The par value of the Common Stock and the Preferred Stock following the Reverse Stock Split shall remain at \$0.00001 per share. The number

of authorized shares of Common Stock and Preferred Stock set forth in the first paragraph of Article Third of this Amendment shall not be affected by, and shall remain unchanged following, the Reverse Stock Split. This reclassification shall apply to all shares of Common Stock outstanding or held in treasury immediately prior to the Stock Split Effective Time.

All certificates representing shares of Common Stock outstanding immediately prior to the Stock Split Effective Time shall thereafter represent instead the number of shares of Common Stock as provided above. Notwithstanding the foregoing, any holder of Common Stock may (but shall not be required to) surrender his, her or its stock certificate or certificates to the Corporation, and upon such surrender the holder may request that the Corporation issue a certificate for the number of shares of Common Stock to which the holder is entitled as a result of the Reverse Stock Split.

No fractional shares shall be issued in connection with the Reverse Stock Split. All shares of Common Stock (including fractions thereof) issuable upon the Reverse Stock Split to a given stockholder of record shall be aggregated for purposes of determining whether the Reverse Stock Split would result in the issuance of a fractional share. If, after the aforementioned aggregation, the Reverse Stock Split would result in the issuance of a fraction of a share of Common Stock to a stockholder of record, the Corporation shall, in lieu of issuing any such fractional share, round down to the nearest whole number of shares in order bring the number of shares held by such stockholder of record down to the nearest whole number of shares of Common Stock. No certificates or book-entries representing fractional shares of Common Stock shall be issued in connection with the Reverse Stock Split. Each certificate or book-entry in favor of a stockholder of record that immediately prior to the Stock Split Effective Time represented shares of Common Stock (each, and "**Old Certificate**"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional share interests as described above.

**FOURTH:** Immediately upon the effectiveness of the Amendment and without further action by the Corporation or any holders thereof, Section 5.1 of Section B of Article Fourth of the Third Amended and Restated Certificate of Incorporation of the Corporation, as amended, shall be amended and restated in its entirety to read as follows:

Each share of Preferred Stock shall automatically be converted into shares of Common Stock, based on the then-applicable Preferred Conversion Price, upon the earlier to occur of the following events: (i) the affirmative election of the holders of a majority of the outstanding shares of Preferred Stock; or (ii) immediately prior to the closing of the sale of shares of Common Stock to the public 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 \$75,000,000 of gross proceeds to the Corporation (the effective time of such affirmative election or the time immediately prior to such closing of the public offering, as applicable, is referred to herein as the "**Mandatory Conversion Time**"). Upon the occurrence of the Mandatory Conversion Time, the following shall occur: (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



Subsection 4.1.1, (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 divided by (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.

*[Remainder of Page Intentionally Left Blank]*

**IN WITNESS WHEREOF**, Harmony Biosciences Holdings, Inc. has caused this Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 10<sup>th</sup> day of August, 2020.

By: /s/ John Jacobs

Name: John Jacobs

Title: President and Chief Executive Officer

330 North Wabash Avenue  
 Suite 2800  
 Chicago, Illinois 60611  
 Tel: +1.312.876.7700 Fax: +1.312.993.9767  
 www.lw.com

**LATHAM & WATKINS** LLP

FIRM / AFFILIATE OFFICES

Beijing	Moscow
Boston	Munich
Brussels	New York
Century City	Orange County
Chicago	Paris
Dubai	Riyadh
Düsseldorf	San Diego
Frankfurt	San Francisco
Hamburg	Seoul
Hong Kong	Shanghai
Houston	Silicon Valley
London	Singapore
Los Angeles	Tokyo
Madrid	Washington, D.C.
Milan	

August 11, 2020

Harmony Biosciences Holdings, Inc.  
 630 W. Germantown Pike, Suite 215  
 Plymouth Meeting, PA 19462

Re: Registration Statement No. 333-240122;  
 5,348,837 of shares of Common Stock, \$0.00001 par value per share

Ladies and Gentlemen:

We have acted as special counsel to Harmony Biosciences Holdings, Inc., a Delaware corporation (the “*Company*”), in connection with the proposed issuance of up to 5,348,837 shares (including shares subject to the underwriters’ option to purchase additional shares) of common stock, \$0.00001 par value per share (the “*Shares*”). The Shares are included in a registration statement on Form S-1 under the Securities Act of 1933, as amended (the “*Act*”), filed with the Securities and Exchange Commission (the “*Commission*”) on July 27, 2020 (Registration No. 333-240122) (as amended, the “*Registration Statement*”). The term “Shares” shall include any additional shares of common stock registered by the Company pursuant to Rule 462(b) under the Act in connection with the offering contemplated by the Registration Statement. This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the General Corporation Law of the State of Delaware and we express no opinion with respect to any other laws.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, upon the proper filing of the third amendment to the third amended and restated

**LATHAM & WATKINS** LLP

certificate of incorporation of the Company, substantially in the form most recently filed as an exhibit to the Registration Statement, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor (not less than par value) and in the circumstances contemplated by the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the General Corporation Law of the State of Delaware.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus under the heading "Legal Matters." We further consent to the incorporation by reference of this letter and consent into any registration statement filed pursuant to Rule 462(b) with respect to the Shares. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ LATHAM & WATKINS LLP

## HARMONY BIOSCIENCES HOLDINGS, INC.

## AMENDED AND RESTATED EQUITY INCENTIVE PLAN

The Board of Directors (the “**Board**”) of Harmony Biosciences Holdings, Inc. (the “**Company**”) has adopted this Amended and Restated Equity Incentive Plan (as amended, the “**Plan**”) as of August [10], 2020 (the “**Effective Date**”) to promote the financial interests of the Company by providing a means by which current and prospective directors, officers, employees, consultants and advisors of the Company and its Affiliates can acquire an equity interest in the Company or be paid incentive compensation measured by the value of the Company’s Common Stock. In addition to the capitalized terms defined elsewhere in this Plan, defined terms shall have the meanings ascribed to them in Section 9.

**1. Term.** The Plan shall continue in effect from the Effective Date through and including the tenth (10<sup>th</sup>) anniversary the Effective Date, unless the Board terminates the Plan prior to such date . Notwithstanding the generality of the foregoing, the Plan shall terminate automatically upon the effectiveness of the Company’s 2020 Incentive Award Plan. No Awards may be granted under the Plan after the termination or expiration of the Plan. However, any Awards that, by their terms, remain outstanding as of the termination or expiration of the Plan shall remain outstanding and in full force and effect, and the terms and conditions of the Plan shall survive its termination or expiration and continue to apply to any such Awards.

**2. Administration.**

(a) The Committee shall administer the Plan. Unless otherwise expressly provided in the Company’s organizational documents, the acts of a majority of the members present at any meeting of the Committee at which a quorum is present, or acts approved in writing by all of the members of the Committee, shall be deemed the acts of the Committee.

(b) Subject to the provisions of the Plan and applicable law, the Committee shall have the sole and plenary authority, in addition to other express powers and authorizations conferred on the Committee by the Plan, to: (i) designate Participants; (ii) determine the type or types of Awards to be granted to Participants; (iii) determine the number of shares of Common Stock to be covered by, or with respect to which payments, rights or other matters are to be calculated in connection with, Awards; (iv) determine the terms and conditions of any Award; (v) grant fully-vested Awards; (vi) determine whether, to what extent and under what circumstances Awards may be settled or exercised in cash, shares of Common Stock, other securities, other Awards or other property; (vii) interpret, administer, reconcile any inconsistency in, correct any defect in and/or supply any omission in the Plan and any instrument or agreement relating to, or Award granted under, the Plan; (viii) establish, amend, suspend or waive any rules and regulations and appoint such agents as the Committee shall deem appropriate for the proper administration of the Plan; (ix) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, Awards; and (x) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of the Plan.

(c) The Committee may delegate to one or more officers of the Company, or of any Affiliate, the authority to act on behalf of the Committee with respect to any matter, right, obligation or election that is the responsibility of, or that is allocated to, the Committee in the Plan and that may be so delegated as a matter of law.

(d) Unless otherwise expressly provided in the Plan, all designations, determinations, interpretations and other decisions under or with respect to the Plan or any Award or any documents evidencing Awards granted pursuant to the Plan shall be made in the sole discretion of the Committee, may

be made at any time and shall be final, conclusive and binding upon all Persons, including the Company, any Affiliate, any Participant, any holder or beneficiary of any Award and any member or stockholder of the Company.

(e) Notwithstanding anything to the contrary contained in the Plan, the Board may, in its sole discretion, at any time, grant Awards and administer the Plan with respect to such Awards. In any such case, the Board shall have all the authority granted to the Committee under the Plan.

### **3. Shares Subject to the Plan; Grant of Awards; Limitations.**

(a) Subject to adjustment pursuant to Section 6, (i) the aggregate number of shares of Common Stock for which Awards may be delivered under the Plan shall not exceed 4,320,876 shares of Common Stock, and (ii) the Committee shall not authorize or make grants of (x) Options or SARs under the Plan in respect of more than 1,623,006 shares of Common Stock to any single Participant during any calendar year, or (y) Incentive Stock Options under the Plan in respect of more than 432,087 shares of Common Stock.

(b) The Committee may grant Awards to any Eligible Person. An Eligible Person may be granted more than one Award under the Plan, and Awards may be granted at any time or times prior to the termination or expiration of the Plan.

(c) The number of shares of Common Stock that are available for Awards under the Plan will include any shares of Common Stock: (i) tendered to the Company by a Participant in payment of any Exercise Price or tax obligations, and (ii) relating to any Awards under the Plan that have been forfeited, cancelled, redeemed, repurchased, expired unexercised or settled in cash.

(d) Shares of Common Stock delivered by the Company in settlement of Awards may be issued by the Company from (i) authorized and unissued shares, (ii) shares held in treasury by the Company, (iii) shares purchased by the Company on the open market or by private purchase, or (iv) any combination of the foregoing.

(e) Awards may, in the sole discretion of the Committee, be granted under the Plan in assumption of, or in substitution for, outstanding awards previously granted by an entity acquired by the Company or with which the Company combines (“**Substitute Awards**”). If the Committee determines that Substitute Awards are to be granted under the Plan, the number of shares of Common Stock underlying any Substitute Awards shall not be counted against the aggregate number of shares of Common Stock available for Awards under the Plan.

### **4. Awards.**

#### **(a) Options.**

(i) Generally. Each Option granted under the Plan shall be subject to the conditions set forth in this Section 4(a), and to such other conditions as may be reflected in the applicable Award agreement or the Plan. All Options granted under the Plan shall be Nonqualified Stock Options unless the applicable Award agreement expressly states that the Option is intended to be an Incentive Stock Option. No Option shall be treated as an Incentive Stock Option unless the Plan has been approved by the stockholders of the Company in a manner intended to comply with the stockholder approval requirements of Section 422(b)(1) of the Code. In the case of an Incentive Stock Option, the terms and conditions of such Award shall be subject to, and comply with such rules as may be prescribed under, Section 422 of the Code. If, for any reason, all or any portion of an Option intended to be an Incentive Stock Option does not qualify as an Incentive Stock Option, then, to the extent of such disqualification, such Option shall be regarded as a Nonqualified Stock Option granted under the Plan.

(ii) *Exercise Price*. Except as otherwise provided by the Committee in the case of Substitute Awards, the exercise price (the “**Exercise Price**”) per share of Common Stock to be issued pursuant to an Option shall not be less than 100% of the Fair Market Value of a share of Common Stock as of the Date of Grant; provided, however, that, in the case of an Incentive Stock Option granted to an employee who, at the time of the grant of such Option, owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate, the Exercise Price per share shall not be less than 110% of the Fair Market Value of a share of Common Stock as of the Date of Grant.

(iii) *Vesting and Expiration*. Options granted under the Plan shall (A) vest and become exercisable in such manner and on such date or dates, and (B) expire after such period, not to exceed ten years from the Date of Grant (the “**Option Period**”), as set forth in an Award agreement; provided, however, that the Option Period shall not exceed five years from the Date of Grant in the case of an Incentive Stock Option granted to a Participant who on the Date of Grant owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate. Notwithstanding any vesting dates set forth in an Award agreement, the Committee may, in its sole discretion, accelerate the vesting and/or exercisability of any Option, which acceleration shall not affect the terms and conditions of such Option other than with respect to vesting and/or exercisability. Unless otherwise provided in an Award agreement, the unvested portion of an Option shall expire upon termination of employment or service of the Participant to whom the Option was granted. Unless otherwise provided in an Award agreement, the vested portion of such Option shall be subject to the following terms:

(1) if such Participant’s employment or service is terminated by reason of such Participant’s death or Disability, then, subject to the terms of Section 6, the portion of such Option that was vested as of the effective date of termination shall remain exercisable until the earlier of (x) the first anniversary of the effective date of termination, and (y) the expiration of the Option Period,

(2) if such Participant’s employment or service is terminated by the Company without Cause, and such Participant has delivered to the Company a general release of claims against the Company, in form and substance acceptable to the Committee, and such release has become irrevocable, then, subject to the terms of Section 6, the portion of such Option that was vested as of the effective date of termination shall remain exercisable until the earlier of (x) ninety (90) days following the effective date of termination, and (y) the expiration of the Option Period, and

(3) if such Participant’s employment or service is terminated for any reason other than as set forth above, including by the Company for Cause or by such Participant for any reason (other than death or Disability), then the portion of such Option that was vested as of the effective date of termination shall automatically expire upon the effective date of termination.

(iv) *Method of Exercise and Form of Payment*. Options that have become exercisable may be exercised by delivery of written notice of exercise to the Company in accordance with the terms of the Option accompanied by payment of the Exercise Price. The Exercise Price shall be payable (A) in cash, promissory notes (to the extent permitted by the Committee and applicable law) and/or shares of Common Stock having a value on the date of exercise equal to the Exercise Price (including pursuant to procedures approved by the Committee, by means of attestation of ownership of a sufficient number of shares of Common Stock in lieu of actual delivery of such shares to the Company), provided, that such shares of Common Stock are not subject to any pledge or other security interest, (B) by a “net exercise” method whereby the Company withholds from the delivery of the shares of Common Stock for which the Option was exercised (or in the case of a public market, uses a broker-assisted cashless exercise of) that

number of shares of Common Stock having a value equal to the aggregate Exercise Price for the shares of Common Stock for which the Option was exercised, or (C) by such other method as the Committee may permit in accordance with applicable law. Any fractional shares of Common Stock shall be settled in cash.

(v) Notification upon Disqualifying Disposition of an Incentive Stock Option. Each Participant awarded an Incentive Stock Option under the Plan shall notify the Company in writing immediately after the date the Participant makes a disqualifying disposition of any shares of Common Stock acquired pursuant to the exercise of such Incentive Stock Option. A disqualifying disposition is any disposition (including any sale) of such shares of Common Stock before the later of (A) two years after the Date of Grant of the Incentive Stock Option or (B) one year after the date of exercise of the Incentive Stock Option. The Company may, if determined by the Committee and in accordance with procedures established by the Committee, retain possession of any shares of Common Stock acquired pursuant to the exercise of an Incentive Stock Option as agent for the applicable Participant until the end of the period described in the preceding sentence.

(b) Stock Appreciation Rights.

(i) Generally. Each SAR granted under the Plan shall be subject to the conditions set forth in this Section 4(b), and to such other conditions as may be reflected in the applicable Award agreement.

(ii) Strike Price. Except as otherwise provided by the Committee in the case of Substitute Awards, the strike price (the “**Strike Price**”) per share of Common Stock for each SAR shall not be less than the Fair Market Value of a share of Common Stock as of the Date of Grant; provided that, in the case of a SAR granted in tandem with an Option, the Strike Price shall not be less than the Exercise Price of the related Option.

(iii) Vesting and Expiration. A SAR granted in tandem with an Option shall become exercisable and shall expire according to the same vesting schedule and expiration provisions as the corresponding Option. A SAR shall (A) vest and become exercisable in such manner and on such date or dates, and (B) expire after such period, not to exceed ten years from the Date of Grant (the “**SAR Period**”), in each case, as set forth in an Award agreement. Notwithstanding any vesting dates set by the Committee in the Award agreement, the Committee may, in its sole discretion, accelerate the vesting and/or exercisability of any SAR, which acceleration shall not affect the terms and conditions of such SAR other than with respect to vesting and/or exercisability. Unless otherwise provided in an Award agreement, the unvested portion of a SAR shall expire upon termination of employment or service of the Participant to whom the SAR was granted. Unless otherwise provided in an Award agreement, the vested portion of such SAR shall be subject to the following terms:

(1) if such Participant’s employment or service is terminated by reason of such Participant’s death or Disability, then, subject to the terms of Section 6, the portion of such SAR that was vested as of the effective date of termination shall remain exercisable until the earlier of (x) the first anniversary of the effective date of termination, and (y) the expiration of the SAR Period,

(2) if such Participant’s employment or service is terminated by the Company without Cause, and such Participant has delivered to the Company a general release of claims against the Company, in form and substance acceptable to the Committee, and such release has become irrevocable, then, subject to the terms of Section 6, the portion of such SAR that was vested as of the effective date of termination shall remain exercisable until the earlier of (x) ninety (90) days following the effective date of termination, and (y) the expiration of the SAR Period, and



(3) if such Participant's employment or service is terminated for any reason other than as set forth above, including by the Company for Cause or by such Participant for any reason (other than death or Disability), then the portion of such SAR that was vested as of the effective date of termination shall automatically expire upon the effective date of termination.

(iv) Method of Exercise and Form of Payment. SARs that have become exercisable may be exercised by delivery of written notice of exercise to the Company in accordance with the terms of the Award, specifying the number of shares subject to the SARs to be exercised. Upon the exercise of any SARs, the Company shall pay to the Participant an amount equal to the number of shares subject to the SARs that are being exercised multiplied by the excess, if any, of the Fair Market Value of a share of Common Stock on the exercise date over the Strike Price, less an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld. Unless otherwise provided in an Award agreement, the Company may pay such amount in cash, in shares of Common Stock with a value equal to such amount, or any combination thereof, as determined by the Committee. Any fractional shares of Common Stock shall be settled in cash.

(c) Restricted Stock and Restricted Stock Units.

(i) Generally. Each grant of Restricted Stock or Restricted Stock Units under the Plan shall be subject to the conditions set forth in this Section 4(c) and to such other conditions as may be reflected in the applicable Award agreement.

(ii) Restricted Stock – Accounts, Escrow or Similar Arrangement. Upon the grant of Restricted Stock, a book entry in a restricted account shall be established in the Participant's name at the Company's transfer agent and, if the Committee determines that the Restricted Stock shall be held by the Company or in escrow rather than held in such restricted account pending the release of the applicable restrictions, the Committee may require the Participant to execute and deliver to the Company (A) an escrow agreement satisfactory to the Committee, if applicable, and (B) an appropriate stock power (endorsed in blank) satisfactory to the Committee with respect to the Restricted Stock covered by such agreement. If a Participant shall fail to execute an agreement evidencing an Award of Restricted Stock and, if applicable, an escrow agreement and blank stock power within the amount of time specified by the Committee, the Award shall be null and void. Subject to the restrictions set forth in this Section 4(c), and unless otherwise set forth in an applicable Award agreement, the Participant generally shall have the rights and privileges of a stockholder as to such Restricted Stock, including the right to vote such Restricted Stock (to the extent such Restricted Stock conveys the right to vote) and the right to receive dividends, if applicable. To the extent shares of Restricted Stock are forfeited, all rights of the Participant to such shares and as a stockholder with respect thereto (and any withheld and accumulated dividends thereon) shall terminate automatically, without further obligation on the part of the Company, and the Participant shall return to the Company promptly any stock certificates issued to the Participant evidencing such shares.

(iii) Vesting; Acceleration of Lapse of Restrictions. The Restricted Period shall lapse with respect to an Award of Restricted Stock or Restricted Stock Units at such times as provided in an Award agreement, and the unvested portion of any Award of Restricted Stock and Restricted Stock Units shall terminate and be forfeited automatically upon termination of employment or service of the Participant.

(iv) Delivery of Restricted Stock; Settlement of Restricted Stock Units.

(1) Upon the expiration of the Restricted Period with respect to any shares of Restricted Stock, the restrictions set forth in the applicable Award agreement shall be of no further force or effect with respect to such shares, except as set forth in the applicable Award agreement. If an escrow arrangement is used, upon such expiration, the Company shall deliver to the Participant, or his or

her beneficiary, without charge, one or more stock certificates evidencing the shares of Restricted Stock that have not then been forfeited and with respect to which the Restricted Period has expired (rounded down to the nearest full share). Dividends, if any, that may have been withheld by the Company and attributable to any particular share of Restricted Stock shall be distributed to the Participant in cash or, at the sole discretion of the Committee, in shares of Common Stock having a Fair Market Value as of the date on which the Restricted Period expired equal to the amount of such dividends, upon the release of restrictions on such share and, if any such shares of Restricted Stock are forfeited, the Participant shall have no right to such dividends (except as otherwise set forth in the applicable Award agreement).

(2) Unless otherwise provided in an Award agreement, upon the expiration of the Restricted Period with respect to any outstanding Restricted Stock Units, the Company shall deliver to the Participant, or his or her beneficiary, without charge, one share of Common Stock for each such outstanding Restricted Stock Unit; provided, however, that the Company may, as determined by the Committee, in its sole discretion, (x) pay cash, or part cash and part shares of Common Stock, in lieu of delivering only shares of Common Stock in respect of such Restricted Stock Units or (y) defer the delivery of shares of Common Stock (or cash, or part shares of Common Stock and part cash, as the case may be) beyond the expiration of the Restricted Period, if such delivery would result in a violation of applicable law, until such time as such payment or delivery would no longer result in a violation of applicable law. If, in settling any Restricted Stock Units, a cash payment is made in lieu of delivering any shares of Common Stock, the amount of such cash payment shall be equal to the Fair Market Value of the corresponding shares of Common Stock as of the date on which the Restricted Period expired. The Committee may grant dividend equivalents in respect of Restricted Stock Units awarded on such terms and conditions as the Committee determines.

(v) Legends on Restricted Stock. As determined by the Committee, in its sole discretion, each certificate representing shares of Restricted Stock awarded under the Plan shall bear a legend in the form and containing such information as the Committee determines appropriate until the lapse of all restrictions with respect to such shares of Restricted Stock.

(d) Stock Bonus Awards. The Committee may issue unrestricted shares of Common Stock, or other Awards denominated in shares of Common Stock, under the Plan to Eligible Persons, either alone or in tandem with other Awards, in such amounts as the Committee shall determine, in its sole discretion (each, a “**Stock Bonus Award**”). Each Stock Bonus Award granted under the Plan shall be subject to such conditions as may be reflected in the applicable Award agreement.

5. *[Reserved.]*

6. *Changes in Capital Structure and Similar Events.*

(a) Effect of Certain Events. In the event of (i) any extraordinary dividend or other extraordinary distribution (whether in the form of cash, shares of Common Stock, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, amalgamation, consolidation, split-up, split-off, combination, repurchase or exchange of shares of Common Stock or other securities of the Company, issuance of warrants or other rights to acquire shares of Common Stock or other securities of the Company, or other similar corporate transaction or event (including a Change in Control) that affects the shares of Common Stock, or (ii) unusual or nonrecurring events (including a Change in Control) affecting the Company, any Affiliate, or the financial statements of the Company or any Affiliate, or changes in applicable rules, rulings, regulations or other requirements of any governmental body or securities exchange or inter-dealer quotation system, accounting principles or law, such that in either case an adjustment is determined by the Committee, in its sole discretion, to be necessary or appropriate, then

the Committee shall make any such adjustments in such manner as it may deem equitable, including any or all of the following:

(i) adjusting any or all of (A) the number of shares of Common Stock or other securities of the Company (or number and kind of other securities or other property) that may be delivered in respect of Awards or with respect to which Awards may be granted under the Plan (including adjusting any or all of the limitations under Section 3 of the Plan) and (B) the terms of any outstanding Award, including (1) the number of shares of Common Stock or other securities of the Company (or number and kind of other securities or other property) subject to outstanding Awards or to which outstanding Awards relate, or (2) the Exercise Price or Strike Price with respect to any Award;

(ii) providing for a substitution or assumption of Awards, accelerating the exercisability of, lapse of restrictions on, or termination of, Awards or providing for a period of time for exercise prior to the occurrence of such event; and

(iii) canceling any one or more outstanding Awards or portion thereof and causing to be paid to the holders thereof, in cash, shares of Common Stock, other securities or other property, or any combination thereof, the value of such Awards, if any, as determined by the Committee (which if applicable may be based upon the price per share of Common Stock received or to be received by other stockholders of the Company in such event), including, in the case of an outstanding Option or SAR, a cash payment in an amount equal to the excess, if any, of the Fair Market Value (as of a date specified by the Committee) of the shares of Common Stock subject to such Option or SAR over the aggregate Exercise Price or Strike Price of such Option or SAR, respectively (it being understood that, in such event, any Option or SAR having a per share Exercise Price or Strike Price equal to, or in excess of, the Fair Market Value of a share of Common Stock subject thereto may be canceled and terminated without any payment or consideration therefor); provided, however, that in the case of any “equity restructuring” (within the meaning of FASB Accounting Standards Codification Topic 718) or any successor rule, the Committee shall make an equitable or proportionate adjustment to outstanding Awards to reflect such equity restructuring. Any adjustment in Incentive Stock Options under this Section 6(a) (other than any cancellation of Incentive Stock Options) shall be made only to the extent not constituting a “modification” within the meaning of Section 424(h)(3) of the Code, and any adjustments under this Section 6(a) shall be made in a manner that does not adversely affect the exemption under Section 409A or the Exchange Act, to the extent applicable. The Company shall give each Participant notice of an adjustment hereunder and, upon notice, such adjustment shall be conclusive and binding for all purposes.

(b) Effect of Change in Control. The effect, if any, of a Change in Control on any Awards outstanding at the time immediately prior to such Change in Control will be as specifically set forth in the corresponding Award agreement, or if no such treatment is specified, then such outstanding Awards shall be subject to any agreement of purchase, merger or reorganization that effects such Change in Control, which agreement shall provide for treatment of such Awards.

(c) No Effect on Authority of the Board or Stockholders. The existence of this Plan and any Awards granted hereunder shall not affect in any way the right or power of the Board or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company’s capital structure or its business, any merger or consolidation of the Company, any issue of debt or equity securities ahead of or affecting Common Stock or the rights thereof, the dissolution or liquidation of the Company or any sale, lease, exchange or other disposition of all or any part of its assets or business or any other corporate act or proceeding.

## 7. *Amendments and Termination.*

(a) Amendment and Termination of the Plan. The Board may amend, alter, suspend, discontinue or terminate the Plan, or any portion thereof, at any time; provided, that (i) no amendment to Section 7(b) (to the extent required by the proviso in such Section 7(b)) shall be made without stockholder approval and (ii) no such amendment, alteration, suspension, discontinuance or termination shall be made without stockholder approval if such stockholder approval is necessary to comply with any tax or regulatory requirement applicable to the Plan (including as necessary to comply with any rules or requirements of any securities exchange or inter-dealer quotation system on which the Common Stock may be listed or quoted); provided, further, that (except as provided above with respect to adjustments by the Committee under Section 6) any such amendment, alteration, suspension, discontinuance or termination that would materially and adversely affect the rights of any Participant or any holder or beneficiary of any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant, holder or beneficiary. Notwithstanding the foregoing, the Committee may amend the Plan, without the consent of any Participant to remedy a potential violation of Code Section 409A.

(b) Amendment of Award Agreements. The Committee may waive any conditions or rights under, amend any terms of, or alter, suspend, discontinue, cancel or terminate, any Award theretofore granted or the associated Award agreement, prospectively or retroactively; provided that any such waiver, amendment, alteration, suspension, discontinuance, cancellation or termination that would materially and adversely affect the rights of any Participant with respect to any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant; provided, further, that, without stockholder approval as may be required by applicable law or the rules of the applicable securities exchange or inter-dealer quotation system on which the Common Stock is listed or quoted, except as otherwise permitted under Section 6, (i) no amendment or modification may reduce the Exercise Price of any Option or the Strike Price of any SAR, (ii) the Committee may not cancel any outstanding Option or SAR and replace it with a new Option or SAR, another Award or cash and (iii) the Committee may not take any other action that is considered a “repricing” for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Common Stock is listed or quoted. No such approval will be required for the items in this Section 7(b)(i) through and including (iii) if stockholder approval is not required by applicable law or such rules.

## 8. *Repurchase.*

(a) Applicability. Except as set forth in an applicable award Agreement, in addition to any terms or conditions provided in any stockholders agreement to which any shares of Common Stock held by a Participant are then subject, any shares of Common Stock held by a Participant (or any subsequent holder of Common Stock granted or issued to such Participant) pursuant to this Plan shall be subject to the repurchase provisions of this Section 8 by the Company (or an designee of the Company). Upon (i) the later of (A) the Participant’s termination of employment or engagement with Company or any of its Affiliates or (B) receipt by the Participant, or Participant’s estate, of underlying Common Stock with respect to an Award or (ii)(A) becoming party to divorce proceedings or (B) Participant’s personal bankruptcy proceedings (each event in (i) or (ii), a “**Triggering Event**”), all of the shares of Common Stock then held by the Participant (or a Permitted Transferee) shall be subject to repurchase by the Company pursuant to this Section 8 (the “**Repurchase Right**”). Without limiting the foregoing, in connection with such Participant becoming party to a divorce proceeding or bankruptcy proceeding (a “**Proceeding**”), the Committee shall have the right to modify the Award to be exercised or settled for cash instead of shares of Common Stock, upon notice to such Participant.

(b) Repurchase Price. The purchase price (“**Repurchase Price**”) for each share of Common Stock being repurchased pursuant to this Section 8 shall be equal to the Fair Market Value of a share of Common Stock as of the date of the Triggering Event, except in the case of a termination of Participant’s employment or engagement with the Company or any of its Affiliates for Cause, in which

case the Repurchase Price will be the lesser of the Fair Market Value of, or the Participant's cash outlay paid (less any distributions received) for, such shares of Common Stock. In respect of any Triggering Event that is not a Proceeding, the Repurchase Price for each restricted share of Common Stock or otherwise unvested share of Restricted Stock being repurchased shall be the lesser of: (i) the amount paid in cash by the Participant for such share of Common Stock (less any distributions made prior to such repurchase in respect of such restricted shares) and (ii) the Fair Market Value of such shares. For the avoidance of doubt, if no purchase price is or was paid in cash for an unvested share of Restricted Stock, then upon the Participant's termination of employment or engagement, such shares of Restricted Stock or otherwise unvested shares of Common Stock under an Award shall be automatically forfeited to the Company without consideration.

(c) Repurchase Notice. The Company (or its designee) may (but shall not be obligated to) elect to purchase all or any portion of the Participant's shares of Common Stock received in respect of Awards under the Plan on the terms contained in this Section 8 by delivering written notice (the "**Repurchase Notice**") to the Participant (or the applicable subsequent holder) within ninety (90) days after the Triggering Event. The Repurchase Notice shall set forth the number of shares of Common Stock to be acquired from the Participant (or Permitted Transferee), the aggregate consideration to be paid for such Common Stock, and the time and place for the closing of such purchase (the "**Closing**").

(d) Repurchase Closing. At the Closing (which, except as provided in this Section 8, shall not occur more than thirty (30) days following delivery of the Repurchase Notice), the Participant (or Permitted Transferee) shall deliver to the Company such documentation as the Company may reasonably require to effect the conveyance to the Company of all of the shares of Common Stock being repurchased, free and clear of all claims, liens or encumbrances. The Company and its Affiliates shall be entitled to offset from amounts payable to the Participant hereunder an amount equal to all (or a portion) of any amounts then owed by the Participant to the Company or any of its Affiliates (so long as such amounts offset are not in violation of Code Section 409A). The Company shall be entitled to receive customary representations and warranties as to ownership, title, authority to sell and the like from the Participant (or the applicable subsequent holder) regarding such sale, to require the Participant's (or the applicable subsequent holder's) signature to be guaranteed and to receive such other evidence, including applicable inheritance and estate tax waivers, as may reasonably be necessary to effect the purchase of the shares of Common Stock. The Company may, at its election, pay the Repurchase Price by delivering a promissory note, payable in four equal annual installments, with the first installment of the Repurchase Price to be paid on the first anniversary of the Closing, and subsequent annual installments to be due and payable on the successive anniversary dates of the Closing. Interest shall accrue from the date of the Closing on the balance of the Repurchase Price remaining unpaid from time to time at the prime rate published in The Wall Street Journal on the date of Closing, and accrued interest shall be payable together with each annual installment of the Repurchase Price. All or part of the Repurchase Price may be prepaid without penalty or premium. Notwithstanding the foregoing, all amounts due shall become immediately due and payable on the tenth (10th) day following a Change in Control. The Company shall be permitted to apply the proceeds of the repurchase of any Common Stock hereunder towards the repayment of any loan or other obligation owed by a Participant to the Company or its Affiliates, including any loan the Participant received in connection with the purchase of the Common Stock under any Award.

(e) Failure to Transfer Shares. If the Participant (or Permitted Transferee) fails, for any reason, to tender any documentation representing the Common Stock to be repurchased hereunder or otherwise fails to comply with this Section 8, the Company may, at its option, in addition to all other remedies it may have, deliver to the Participant (or Permitted Transferee) the purchase price for such Common Stock as is herein specified (which may include a promissory note). The Company then shall cancel on its books the documentation representing the Common Stock to be repurchased and all of the Participant's (or the applicable subsequent holder's) rights in and to such Common Stock shall terminate

without the need for further action of the Participant. If the Company (or its designee) does not repurchase all of the Participant's (or the applicable subsequent holder's) Common Stock as provided in this Section 8, the Company will modify its documentation to accurately represent the Participant's (or Permitted Transferee's) continued ownership of the Common Stock that the Company (or its designee) did not repurchase.

(f) Tolling. Notwithstanding anything to the contrary in an Award agreement or herein, the Company may toll the Closing if it determines that (i) the purchase of such Common Stock (whether or not together with any other purchases of shares of Common Stock), would result (A) in a violation of any applicable law or (B) after giving effect thereto, in a violation of any then-existing credit or similar agreements of the Company or its Affiliates, (ii) there exists a violation of a credit or other agreement binding upon any the Company or its Affiliates which could reasonably be expected to prohibit such issuance or purchase, (iii) the Company does not have funds available and appropriate to effect such purchase, or (iv) the consent of any legal, judicial, regulatory, or other governmental entity is required to consummate such redemption or repurchase. The Company shall, upon making any such determination, notify the Participant that it will not purchase such Common Stock at such time as specified in the Repurchase Notice and has deferred its right to make such purchase until such (x) consent is obtained or (y) violation of applicable law or credit agreement or unavailability of funds would not, as applicable, result therefrom or has ceased.

(g) Cooperation. In the event that Common Stock is to be repurchased pursuant to this Section 8, as a condition to receipt of any Award, the Participant will take all steps necessary and desirable to obtain all required third-party, governmental and regulatory consents and approvals and take all other actions necessary and desirable to facilitate consummation of such repurchase(s) in a timely manner.

**9. Definitions.** In addition to the capitalized terms defined throughout the Plan, except as otherwise defined in an Award agreement or an overriding written agreement between the Company and a Participant, the following capitalized terms shall have the corresponding meanings set forth in this Section 9:

(a) "Affiliate" means any parent or direct or indirect subsidiary of the Company; provided, that, with respect to Incentive Stock Options, the term shall only mean "parent corporation" and "subsidiary corporation" as defined in Sections 424(e) and 424(f) of the Code; further, provided, that, with respect to the award of any "stock right" within the meaning of Section 409A of the Code, such affiliate must qualify as a "service recipient" within the meaning of Section 409A of the Code and in applying Section 1563(a)(1), (2) and (3) of the Code for purposes of determining a controlled group of corporations under Section 414(b) of the Code and in applying Treasury Regulation Section 1.414(c)-2 for purposes of determining trades or businesses (whether or not incorporated) that are under common control for purposes of Section 414(c) of the Code, the language "at least 50 percent" is used instead of "at least 80 percent."

(b) "Award" means any SAR, Incentive Stock Option, Nonqualified Stock Option, Restricted Stock, Restricted Stock Unit or Stock Bonus Award granted under the Plan.

(c) "Cause" means, in the case of a particular Award, unless the applicable Award agreement states otherwise, (i) the Company or an Affiliate having "cause" to terminate a Participant's employment or service, as defined in any employment or consulting agreement or similar services agreement between the Participant and the Company or an Affiliate in effect at the time of such termination or (ii) in the absence of any such employment, consulting, or similar services agreement (or the absence of any definition of "Cause" contained therein), the Participant's (A) material breach of his or her obligations under any agreement or arrangement entered into with the Company or its Affiliates (which remains uncured (to the extent the Committee reasonably determines curable) for at least ten (10) days following

notice of such breach); (B) gross negligence or willful misconduct in the performance of or non-performance of his or her duties to the Company or its Affiliates; (C) breach of any of the Company's or its Affiliates' written policies or procedures in each case in any respect which causes or is reasonably expected to cause harm to the Company or any Affiliate; (D) commission of a felony or a crime of moral turpitude (or the procedural equivalent of the foregoing); (E) commission of an act involving deceit, fraud, perjury or embezzlement involving the Company or its Affiliates or any client, customer, supplier or business relationship of the Company or any Affiliate; (F) repeatedly being under the influence of drugs or alcohol (other than over-the-counter or prescription medicine or other medically-related drugs to the extent they are taken in accordance with their directions or under the supervision of a physician) which inhibits the performance of such Participant's duties to the Company or its Affiliates, or, while under the influence of such drugs or alcohol, engaging in inappropriate conduct during the performance of his or her duties to the Company or its Affiliates; or (G) failure to follow lawful directives of the Participant's supervisor, which (which failure remains uncured (to the extent the Committee reasonably determines curable) for at least ten (10) days following initial notice of such failure). Any rights to cure that are expressly described in this definition will only be afforded for the initial occurrence of any purported grounds of Cause and the Participant will not have any right (unless the Committee otherwise determines) to cure such purported grounds. Any determination of whether Cause exists shall be made by the Committee in its sole discretion.

(d) "Change in Control," in the case of a particular Award, unless the applicable Award agreement states otherwise or contains a different definition of "Change in Control," means (i) the sale, lease, transfer, conveyance or other disposition, in one transaction or a series of related transactions, of all or substantially all of the assets of the Company, (ii) the sale, transfer, conveyance or other disposition, in one transaction or a series of related transactions, of the outstanding equity securities of the Company, and (iii) the merger or consolidation of the Company with another Person, in each case in clauses (ii) and (iii) above under circumstances in which the holders of the voting power of outstanding equity securities of the Company, immediately prior to such transaction, are no longer, in the aggregate, the beneficial owners (within the meaning of Rule 13d-3 of the Exchange Act), directly or indirectly through one or more intermediaries, of more than fifty percent (50%) of the voting power of the outstanding equity securities of the surviving or resulting corporation or acquirer, as the case may be, immediately following such transaction. A sale (or multiple related sales) of one or more Subsidiaries (whether by way of merger, consolidation, reorganization or sale of all or substantially all of the assets or securities) which constitutes all or substantially all of the consolidated assets of the Company shall be deemed a Change in Control. In addition, notwithstanding anything herein to the contrary, in any circumstance in which the definition of "Change in Control" under this Plan would otherwise be operative and with respect to which the additional tax under Section 409A of the Code would apply or be imposed, but where such tax would not apply or be imposed if the meaning of the term "Change in Control" met the requirements of Section 409A(a)(2)(A)(v) of the Code, then the term "Change in Control" herein shall mean, but only for the transaction, event or circumstance so affected and the item of income with respect to which the additional tax under Section 409A of the Code would otherwise be imposed, a transaction, event or circumstance that is both (x) described in the preceding provisions of this definition, and (y) a "change in control event" within the meaning of Treasury Regulations Section 1.409A-3(i)(5). Notwithstanding the foregoing, in the case of a particular Award, unless the applicable Award agreement states otherwise or contains a different definition of "Change in Control," the sale or transfer of equity securities in a Public Offering shall not be considered in determining whether a transaction constitutes a Change in Control.

(e) "Code" means the Internal Revenue Code of 1986, as amended, and any successor thereto. Reference in the Plan to any section of the Code shall be deemed to include any regulations or other interpretative guidance under such section, and any amendments or successor provisions to such section, regulations or guidance.

(f) “Committee” means the Compensation Committee, as constituted from time to time, of the Board, or if no such committee shall be in existence at any relevant time, the term “Committee” for purposes of the Plan shall mean the Board.

(g) “Common Stock” means the common stock of the Company par value \$0.0001 (and any stock or other securities into which such shares of common stock may be converted or into which they may be exchanged).

(h) “Date of Grant” means the date on which the granting of an Award is authorized, or such other date as may be specified in such authorization; provided, however, that such date complies with the requirements of Sections 422 and 409A of the Code, as applicable.

(i) “Disability” means (except as expressly provided in the Participant’s Award agreement, or in the case of Incentive Stock Options, in which case, Disability shall have the definition attributed to a permanent disability in Section 22(e)(3) of the Code), the Participant’s inability to perform the essential functions of such Participant’s service due to a medically determinable physical or mental impairment, which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve months; provided, however, that a Participant shall be deemed to have a Disability if he or she is determined to be totally disabled by the U.S. Social Security Administration.

(j) “Eligible Person” means any (i) employee of the Company or any Affiliate; (ii) director of the Company or any Affiliate; (iii) consultant or advisor to the Company or any Affiliate; or (iv) prospective employee, director, officer, consultant or advisor who has accepted an offer of employment, engagement or consultancy from the Company or any Affiliate, and who would satisfy the provisions of clauses (i) through (iii) above once he or she begins employment with or begins providing services to the Company or any Affiliate.

(k) “Exchange Act” means the Securities Exchange Act of 1934, as amended, and any reference in the Plan to any section of (or rule promulgated under) the Exchange Act shall be deemed to include any rules, regulations or other interpretative guidance under such section or rule, and any amendments or successor provisions to such section, rules, regulations or guidance.

(l) “Fair Market Value” means, as of any date, the fair market value of a share of Common Stock, determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Committee deems reliable or (ii) without an established market for the Common Stock, the Committee will determine the Fair Market Value in its discretion; provided, that for purposes of setting an Exercise Price or Strike Price, as applicable, Fair Market Value will be determined in accordance with Code Section 409A and Treasury Regulation Section 1.409A-1(b)(5).

(m) “Incentive Stock Option” means an Option that is designated by the Committee as an incentive stock option as described in Section 422 of the Code and otherwise meets the requirements set forth in the Plan and Section 422 of the Code.

(n) “Nonqualified Stock Option” means an Option that is not designated by the Committee as an Incentive Stock Option.

(o) “Option” means an option to purchase shares of Common Stock, which will either be an Incentive Stock Option or a Nonqualified Stock Option.



(p) “Participant” means an Eligible Person who has been selected by the Committee to participate in the Plan and to receive an Award.

(q) “Permitted Transferee” means, with respect to a Participant, (i) any person who is a “family member” of the Participant, as such term is used in the instructions to Form S-8 under the Securities Act (collectively, the “Immediate Family Members”); (ii) a trust solely for the benefit of the Participant and his or her Immediate Family Members; (iii) a partnership or limited liability company whose only partners or stockholders are the Participant and his or her Immediate Family Members; or (iv) any other transferee as may be approved either (A) by the Board or the Committee in its sole discretion, or (B) as provided in the applicable Award agreement.

(r) “Person” means any individual or entity, including a corporation, partnership, association, limited liability company, limited liability partnership, joint-stock company, trust, unincorporated association, government or governmental agency or authority.

(s) “Public Offering” means any sale of the Company’s Common Stock or other equity securities pursuant to a registration statement filed with the Securities Exchange Commission under the Securities Act.

(t) “Restricted Period” means the period of time determined by the Committee during which an Award is subject to restrictions or, as applicable, the period of time within which performance is measured for purposes of determining whether an Award has been earned.

(u) “Restricted Stock Unit” means an unfunded and unsecured promise to deliver shares of Common Stock, cash, other securities or other property, subject to certain restrictions (including, without limitation, a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 4(c) of the Plan.

(v) “Restricted Stock” means shares of Common Stock, subject to certain specified restrictions (including a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 4(c) of the Plan.

(w) “SAR” means a stock appreciation right granted under Section 4(b) of the Plan.

(x) “Securities Act” means the Securities Act of 1933, as amended, and any successor thereto. Reference in the Plan to any section of the Securities Act shall be deemed to include any rules, regulations or other interpretative guidance under such section, and any amendments or successor provisions to such section, rules, regulations or guidance.

(y) “Subsidiary” means, with respect to any specified Person:

(i) any corporation, association or other business entity of which more than 50% of the total voting power of shares or any equivalent equity-type ownership (without regard to the occurrence of any contingency and after giving effect to any voting agreement or stockholders’ agreement that effectively transfers voting power) is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person (or a combination thereof); and

(ii) any partnership (or any comparable foreign entity) (A) the sole general partner (or functional equivalent thereof) or the managing general partner of which is such Person or a Subsidiary of such Person or (B) the only general partners (or functional equivalents thereof) of which are that Person or one or more Subsidiaries of that Person (or any combination thereof).

**10. [Reserved.]**

**11. General.**

(a) Award Agreements. Each Award under the Plan shall be evidenced by an Award agreement, which shall be delivered to the Participant (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)) and shall specify the terms and conditions of the Award and any rules applicable thereto.

(b) Nontransferability.

(i) Each Award shall be exercisable only by a Participant during the Participant's lifetime, or, if permissible under applicable law, by the Participant's legal guardian or representative. No Award may be assigned, alienated, pledged, attached, sold or otherwise transferred or encumbered by a Participant other than by will or by the laws of descent and distribution and any such purported assignment, alienation, pledge, attachment, sale, transfer or encumbrance shall be void and unenforceable against the Company or an Affiliate; provided that the designation of a beneficiary in accordance with Section 11(f) shall not constitute an assignment, alienation, pledge, attachment, sale, transfer or encumbrance.

(ii) Notwithstanding the foregoing, the Committee may, in its sole discretion, permit Awards (other than Incentive Stock Options) to be transferred by a Participant, without consideration, to a Permitted Transferee, subject to such rules as the Committee may adopt consistent with any applicable Award agreement to preserve the purposes of the Plan; provided, that the Participant gives the Committee advance written notice describing the terms and conditions of the proposed transfer, and the Committee notifies the Participant in writing that such a transfer would comply with the requirements of the Plan.

(iii) The terms of any Award transferred in accordance with the immediately preceding sentence shall apply to the Permitted Transferee, and any reference in the Plan, or in any applicable Award agreement, to a Participant shall be deemed to refer to the Permitted Transferee, except that (A) Permitted Transferees shall not be entitled to transfer any Award, other than by will or the laws of descent and distribution; (B) Permitted Transferees shall not be entitled to exercise any transferred Option unless there shall be in effect a registration statement on an appropriate form covering the Common Stock to be acquired pursuant to the exercise of such Option if the Committee determines, consistent with any applicable Award agreement, that such a registration statement is necessary or appropriate; (C) the Committee or the Company shall not be required to provide any notice to a Permitted Transferee, whether or not such notice is or would otherwise have been required to be given to the Participant under the Plan or otherwise; and (D) the consequences of the termination of the Participant's employment by, or services to, the Company or an Affiliate under the terms of the Plan and the applicable Award agreement shall continue to be applied with respect to the Participant, including that an Option shall be exercisable by the Permitted Transferee only to the extent, and for the periods, specified in the Plan and the applicable Award agreement.

(c) Tax Withholding.

(i) A Participant shall be required to pay to the Company or any Affiliate, and the Company or any Affiliate shall have the right and is hereby authorized to withhold, from any cash, shares of Common Stock, other securities or other property deliverable under any Award or from any compensation or other amounts owing to a Participant, the amount (in cash, shares of Common Stock, other securities or other property) of any required withholding taxes in respect of an Award, its exercise, or any payment or transfer under an Award or under the Plan and to take such other action as may be necessary in the opinion of the Committee or the Company to satisfy all obligations for the payment of such withholding taxes.

(ii) Without limiting the generality of clause (i) above, the Committee may permit a Participant to satisfy, in whole or in part, the foregoing withholding liability by (A) the delivery of shares of Common Stock (which are not subject to any pledge or other security interest) owned by the Participant having a Fair Market Value equal to such withholding liability or (B) having the Company withhold from the number of shares of Common Stock otherwise issuable or deliverable pursuant to the exercise or settlement of the Award a number of shares with a Fair Market Value equal to such withholding liability (but no more than the minimum required statutory withholding liability).

(d) No Claim to Awards; No Rights to Continued Employment; Waiver. No employee of the Company or an Affiliate, or other Person, shall have any claim or right to be granted an Award under the Plan or, having been selected for the grant of an Award, to be selected for a grant of any other Award. There is no obligation for uniformity of treatment of Participants or holders or beneficiaries of Awards. The terms and conditions of Awards and the Committee's determinations and interpretations with respect thereto need not be the same with respect to each Participant and may be made selectively among Participants, whether or not such Participants are similarly situated. Neither the Plan nor any action taken hereunder shall be construed as giving any Participant any right to be retained in the employ or service of the Company or an Affiliate, nor shall it be construed as giving any Participant any rights to continued service on the Board. The Company and any of its Affiliates may at any time dismiss a Participant from employment or discontinue any consulting relationship, free from any liability or any claim under the Plan, unless otherwise expressly provided in the Plan or any Award agreement. By accepting an Award under the Plan, a Participant shall thereby be deemed to have waived any claim to continued exercise or vesting of an Award or to damages or severance entitlement related to non-continuation of the Award beyond the period provided under the Plan or any Award agreement, notwithstanding any provision to the contrary in any written employment contract or other agreement between the Company and its Affiliates and the Participant, whether any such agreement is executed before, on or after the Date of Grant.

(e) International Participants. With respect to Participants who reside or work outside of the United States of America, the Committee may in its sole discretion amend the terms of the Plan or outstanding Awards (or adopt a subplan) with respect to such Participants in order to conform such terms with the requirements of local law or to obtain more favorable tax or other treatment for a Participant, the Company or its Affiliates.

(f) Designation and Change of Beneficiary. Each Participant may file with the Committee a written designation of one or more persons as the beneficiary(ies) who shall be entitled to receive the amounts payable with respect to an Award, if any, due under the Plan upon his or her death. A Participant may, from time to time, revoke or change his or her beneficiary designation without the consent of any prior beneficiary by filing a new designation with the Committee. The last such designation received by the Committee shall be controlling; provided, however, that no designation, or change or revocation thereof, shall be effective unless received by the Committee prior to the Participant's death, and in no event shall it be effective as of a date prior to such receipt. If no beneficiary designation is filed by a Participant, the beneficiary shall be deemed to be his or her spouse at the time of death or, if the Participant is unmarried at the time of death, his or her estate. Notwithstanding anything herein to the contrary, to the extent that a Participant's beneficiary designation would result in a duplication of, or unintended, benefits payable under this Plan or would otherwise violate applicable law, the Committee shall have the authority to disregard such designation and payments shall be made in accordance with applicable law.

(g) Termination of Employment/Service. Unless determined otherwise by the Committee at any point following such event or as otherwise provided in an Award agreement, service shall not be considered terminated in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Affiliate, or any successor, in any capacity of any employee, director or consultant, or (iii) any change in status as long as the individual remains in the service of the Company or an Affiliate in any capacity of employee, director or consultant. An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave. For purposes of each Incentive Stock Option, if such leave exceeds three (3) months, and re-employment upon expiration of such leave is not guaranteed by statute or contract, then the Incentive Stock Option shall be treated as a Nonqualified Stock Option on the day following the expiration of such three (3) month period.

(h) No Rights as a Stockholder. Except as otherwise specifically provided in the Plan or any Award agreement, no person shall be entitled to the privileges of ownership in respect of shares of Common Stock that are subject to Awards hereunder until such shares have been issued or delivered to that person. The Committee may require each Participant purchasing or receiving shares of Common Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring Common Stock without a view to the distribution thereof.

(i) Government and Other Regulations/Limitations.

(i) The Plan is intended to be a “compensatory benefit plan” within the meaning of such term under Rule 701 of the Securities Act. Grants of Awards pursuant to the Plan (and the issuance of shares of Common Stock upon the exercise of any Options) are intended to qualify for an exemption from the registration requirements under the Securities Act pursuant to Rule 701 and under analogous provisions of applicable state securities laws (collectively, the “**Registration Exemptions**”). In the event that any provision of the Plan would cause any Award or Option granted pursuant to the Plan to not qualify for the Registration Exemptions, the Plan will be deemed to be amended automatically to the extent necessary to cause all such Awards and Options to qualify for the Registration Exemptions.

(ii) The obligation of the Company to settle Awards in shares of Common Stock or other consideration shall be subject to all applicable laws, rules, and regulations, and to such approvals by governmental agencies as may be required. Notwithstanding any terms or conditions of any Award to the contrary, the Company shall be under no obligation to offer to sell or to sell, and shall be prohibited from offering to sell or selling, any shares of Common Stock pursuant to an Award unless such shares have been properly registered for sale pursuant to the Securities Act with the Securities and Exchange Commission or unless the Company has received an opinion of counsel, satisfactory to the Company, that such shares may be offered or sold without such registration pursuant to an available exemption therefrom and the terms and conditions of such exemption have been fully complied with. The Company shall be under no obligation to register for sale under the Securities Act any of the shares of Common Stock to be offered or sold under the Plan. The Committee shall have the authority to provide that all certificates for shares of Common Stock or other securities of the Company or any Affiliate delivered under the Plan shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under the Plan, the applicable Award agreement, the federal securities laws, or the rules, regulations and other requirements of the Securities and Exchange Commission, any securities exchange or inter-dealer quotation system upon which such shares or other securities are then listed or quoted and any other applicable federal, state, local or non-U.S. laws, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions. Notwithstanding any provision in the Plan to the contrary, the Committee reserves the right to add any additional terms or provisions to any Award granted under the Plan that it in its sole discretion deems necessary or advisable in order that such Award complies with the legal requirements of any governmental entity to whose jurisdiction the Award is subject.

(iii) The Committee may toll the exercise or settlement of an Award or any portion thereof if it reasonably determines that legal or contractual restrictions and/or blockage and/or other market considerations would make the Company's acquisition of shares of Common Stock from the public markets, the Company's issuance of shares of Common Stock to the Participant, the Participant's acquisition of shares of Common Stock from the Company and/or the Participant's sale of shares of Common Stock to the public markets, illegal, impracticable or inadvisable.

(j) Payments to Persons Other Than Participants. If the Committee shall find that any Person to whom any amount is payable under the Plan is unable to care for his affairs because of illness or accident, or is a minor, or has died, then any payment due to such person or his estate (unless a prior claim therefor has been made by a duly appointed legal representative) may, if the Committee so directs the Company, be paid to his or her spouse, child, relative, an institution maintaining or having custody of such Person, or any other Person deemed by the Committee to be a proper recipient on behalf of such Person otherwise entitled to payment. Any such payment shall be a complete discharge of the liability of the Committee and the Company therefor.

(k) Nonexclusivity of the Plan. Neither the adoption of this Plan by the Board nor the submission of this Plan to the stockholders of the Company for approval shall be construed as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock options or other equity-based awards otherwise than under this Plan, and such arrangements may be either applicable generally or only in specific cases.

(l) No Trust or Fund Created. Neither the Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company or any Affiliate, on the one hand, and a Participant or other Person, on the other hand. No provision of the Plan or any Award shall require the Company, for the purpose of satisfying any obligations under the Plan, to purchase assets or place any assets in a trust or other entity to which contributions are made or otherwise to segregate any assets, nor shall the Company maintain separate bank accounts, books, records or other evidence of the existence of a segregated or separately maintained or administered fund for such purposes. Participants shall have no rights under the Plan other than as unsecured general creditors of the Company, except that insofar as they may have become entitled to payment of additional compensation by performance of services, they shall have the same rights as other employees under general law. This Plan is not subject to the federal Employee Retirement Income Security Act of 1974, as amended (ERISA).

(m) Reliance on Reports. Each member of the Committee and each member of the Board shall be fully justified in acting or failing to act, as the case may be, and shall not be liable for having so acted or failed to act in good faith, in reliance upon any report made by the independent public accountant of the Company and its Affiliates and/or any other information furnished in connection with the Plan by any agent of the Company or the Committee or the Board, other than himself or herself.

(n) Relationship to Other Benefits. No payment under the Plan shall be taken into account in determining any benefits under any pension, retirement, profit sharing, group insurance or other benefit plan of the Company except as otherwise specifically provided in such other plan.

(o) Governing Law. The Plan shall be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to the conflict of laws provisions.

(p) Severability. If any provision of the Plan or any Award or Award agreement is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction or as to any person or entity or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to the applicable laws, or if it cannot be construed or deemed amended without, in the determination of the Committee, materially altering the intent of the Plan or the Award, such provision shall be construed or deemed stricken as to such jurisdiction, person or entity or Award and the remainder of the Plan and any such Award shall remain in full force and effect.

(q) Obligations Binding on and Inurement to Successors. The obligations of the Company under the Plan shall be binding upon and inure to the benefit of any successor corporation or organization resulting from the merger, amalgamation, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company.

(r) [Reserved.]

(s) Expenses; Gender; Titles and Headings. The expenses of administering the Plan shall be borne by the Company and its Affiliates. Masculine pronouns and other words of masculine gender shall refer to both men and women. The titles and headings of the sections in the Plan are for convenience of reference only, and in the event of any conflict, the text of the Plan, rather than such titles or headings shall control.

(t) Other Agreements. Notwithstanding anything herein or in any Award agreement to the contrary, in no event will shares of Common Stock be delivered upon vesting, exercise or settlement of any Award granted under the Plan unless and until the Participant, as requested by the Committee, executes a joinder (or similar arrangement) whereby such Participant will become bound by the terms and conditions set forth in any stockholder agreements then applicable to the holders of the Company's Common Stock (other than de minimis holders, i.e., holders of less than one percent (1%) of the Company's Common Stock calculated on a fully-diluted basis), such that the Participant shall be subject to (i) the same obligations, including with respect to drag-along obligations, rights of first refusal, voting agreements, and lock-up agreements, on the same terms and conditions as are then applicable to such holders of the Company's Common Stock and (ii) other customary restrictions that are applicable to officers and directors of the Company as a matter of law or in connection with a public offering of the Company's Common Stock.

(u) Payments. Participants shall be required to pay, to the extent required by applicable law, any amounts required to receive shares of Common Stock under any Award made under the Plan.

(v) Section 409A. The Plan and the Awards hereunder are intended to either comply with, or be exempt from, the requirements of Section 409A of the Code. To the extent that the Plan or any Award is not exempt from the requirements of Section 409A of the Code, the Plan and any such Award intended to comply with the requirements of Section 409A of the Code shall be limited, construed and interpreted in accordance with such intent. Notwithstanding the foregoing, in no event whatsoever shall the Company be liable for any additional tax, interest or penalty that may be imposed by Section 409A of the Code or any damages relating to any failure to comply with Section 409A of the Code. Each payment or benefit under the Plan shall constitute a separate payment for purposes of Section 409A of the Code.

(w) Offset. Any amounts owed to the Company or an Affiliate by a Participant of whatever nature may be offset by the Company from the value of any Common Stock, cash or other thing of value under this Plan or an agreement to be transferred to the Participant, and no Common Stock, cash or other thing of value under this Plan or an agreement shall be transferred unless and until all disputes between the Company (or its Affiliates) and the Participant have been fully and finally resolved and the Participant has waived all claims to such against the Company and any Affiliate. Any such offset or delay will be made in a manner that does not violate Section 409A of the Code, as may be applicable.

(x) Data Privacy. As a condition of receipt of any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this subsection by and among, as applicable, the Company and its Affiliates for the exclusive purpose of implementing, administering and managing the Participant's participation in this Plan. The Company and its Affiliates may hold certain personal information about a Participant, including but not limited to, the Participant's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering this Plan and Awards (the "Data"). The Company and its Affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant's participation in this Plan, and the Company and its Affiliates may each further transfer the Data to any third parties assisting the Company and its Affiliates in the implementation, administration and management of this Plan. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in this Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or its Affiliates, or the Participant, may elect to deposit any Common Stock. The Data related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant's participation in this Plan. A Participant may, at any time, view the Data held by the Company or its Affiliates with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative.

(y) Expiration. Awards may only be exercised in accordance with the terms of the applicable Award agreement and/or the Plan, and no Award will be automatically exercised, including in connection with the expiration thereof. Participants are required to exercise any Awards, subject to their terms, in a manner consistent with the terms of the Plan including this Section 11(y). Any Awards not so exercised will expire without being exercised or the payment of consideration or proceeds therefor. The Company and its Affiliates will not be obligated to notify Participants of Awards that are expiring and will have no liability for any Awards that expire unexercised.

\*\*\*

**HARMONY BIOSCIENCES HOLDINGS, INC.****2020 INCENTIVE AWARD PLAN****ARTICLE I.  
PURPOSE**

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities and/or equity-linked compensatory opportunities. Capitalized terms used in the Plan are defined in Article XI.

**ARTICLE II.  
ELIGIBILITY**

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

**ARTICLE III.  
ADMINISTRATION AND DELEGATION**

3.1 Administration. The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award Agreement as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.

3.2 Appointment of Committees. To the extent Applicable Laws permit, the Board or the Administrator may delegate any or all of its powers under the Plan to one or more Committees or committees of officers of the Company or any of its Subsidiaries. The Board or the Administrator, as applicable, may rescind any such delegation, abolish any such committee or Committee and/or re-vest in itself any previously delegated authority at any time.

**ARTICLE IV.  
STOCK AVAILABLE FOR AWARDS**

4.1 Number of Shares. Subject to adjustment under Article VIII and the terms of this Article IV, the maximum number of Shares that may be issued pursuant to Awards under the Plan shall be equal to the Overall Share Limit. As of the Effective Date, the Company will cease granting awards under the Prior Plan; however, Prior Plan Awards will remain subject to the terms of the applicable Prior Plan. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

4.2 Share Recycling. If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the



Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award or Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Award grants under the Plan. In addition, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award or Prior Plan Award and/or to satisfy any applicable tax withholding obligation with respect to an Award (including Shares retained by the Company from the Award or Prior Plan Award being exercised or purchased and/or creating the tax obligation) will, as applicable, become or again be available for Award grants under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not count against the Overall Share Limit. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added to the Shares authorized for grant under Section 4.1 and shall not be available for future grants of Awards: (i) Shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right on exercise thereof; and (ii) Shares purchased on the open market with the cash proceeds from the exercise of Options.

4.3 Incentive Stock Option Limitations. Notwithstanding anything to the contrary herein, no more than 35,000,000 Shares may be issued pursuant to the exercise of Incentive Stock Options.

4.4 Substitute Awards. In connection with an entity's merger or consolidation with the Company or the Company's acquisition of an entity's property or stock, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate. Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Substitute Awards will not count against the Overall Share Limit (nor shall Shares subject to a Substitute Award be added to the Shares available for Awards under the Plan as provided above), except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided above); provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not Employees, Consultants or Directors prior to such acquisition or combination.

4.5 Non-Employee Director Compensation. Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee Director as compensation for services as a non-employee Director during any fiscal year of the Company may not exceed \$750,000 increased to \$1,000,000 in the fiscal year of a non-employee Director's initial service as a non-employee Director (the "**Director Limit**").

**ARTICLE V.**  
**STOCK OPTIONS AND STOCK APPRECIATION RIGHTS**

5.1 General. The Administrator may grant Options or Stock Appreciation Rights to Service Providers subject to the limitations in the Plan, including any limitations in the Plan that apply to Incentive Stock Options. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

5.2 Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. The exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option (subject to Section 5.6) or Stock Appreciation Right. Notwithstanding the foregoing, in the case of an Option or a Stock Appreciation Right that is a Substitute Award, the exercise price per share of the Shares subject to such Option or Stock Appreciation Right, as applicable, may be less than the Fair Market Value per share on the date of grant; *provided that* the exercise price of any Substitute Award shall be determined in accordance with the applicable requirements of Sections 424 and 409A of the Code.

5.3 Duration. Each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that, subject to Section 5.6, the term of an Option or Stock Appreciation Right will not exceed ten years. Notwithstanding the foregoing and unless determined otherwise by the Company, in the event that on the last business day of the term of an Option or Stock Appreciation Right (other than an Incentive Stock Option) (i) the exercise of the Option or Stock Appreciation Right is prohibited by Applicable Law, as determined by the Company, or (ii) Shares may not be purchased or sold by the applicable Participant due to any Company insider trading policy (including blackout periods) or a "lock-up" agreement undertaken in connection with an issuance of securities by the Company, the term of the Option or Stock Appreciation Right shall be extended until the date that is 30 days after the end of the legal prohibition, black-out period or lock-up agreement, as determined by the Company; provided, however, in no event shall the extension last beyond the ten year term of the applicable Option or Stock Appreciation Right. Notwithstanding the foregoing, to the extent permitted under Applicable Laws, if the Participant, prior to the end of the term of an Option or Stock Appreciation Right, violates the non-competition, non-solicitation, confidentiality or other similar restrictive covenant provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company or any of its Subsidiaries, the right of the Participant and the Participant's transferees to exercise any Option or Stock Appreciation Right issued to the Participant shall terminate immediately upon such violation, unless the Company otherwise determines.

5.4 Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full (i) as specified in Section 5.5 for the number of Shares for which the Award is exercised and (ii) as specified in Section 9.5 for any applicable taxes. Unless the Administrator otherwise determines, an Option or Stock Appreciation Right may not be exercised for a fraction of a Share.

5.5 Payment Upon Exercise. Subject to Section 10.8, any Company insider trading policy (including blackout periods) and Applicable Laws, the exercise price of an Option must be paid by:

(a) cash, wire transfer of immediately available funds or by check payable to the order of the Company, provided that the Company may limit the use of one of the foregoing payment forms if one or more of the payment forms below is permitted;

(b) if there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;

(c) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;

(d) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(e) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or

(f) to the extent permitted by the Company, any combination of the above payment forms approved by the Administrator.

5.6 Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Stockholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within (i) two years from the grant date of the Option or (ii) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code. Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the \$100,000 limitation under Treasury Regulation Section 1.422-4, will be a Non-Qualified Stock Option.

**ARTICLE VI.  
RESTRICTED STOCK; RESTRICTED STOCK UNITS**

6.1 General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the Company's right to repurchase all or part of such Shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such Shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement.

6.2 Restricted Stock.

(a) Dividends. Participants holding Shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such Shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the Shares of Restricted Stock with respect to which they were paid. Notwithstanding anything to the contrary herein, with respect to any award of Restricted Stock, dividends which are paid to holders of Common Stock prior to vesting shall only be paid out to the Participant holding such Restricted Stock to the extent that the vesting conditions are subsequently satisfied. All such dividend payments will be made no later than March 15 of the calendar year following the calendar year in which the right to the dividend payment becomes nonforfeitable.

(b) Stock Certificates. The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of Shares of Restricted Stock, together with a stock power endorsed in blank.

6.3 Restricted Stock Units.

(a) Settlement. The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.

(b) Stockholder Rights. A Participant will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

**ARTICLE VII.  
OTHER STOCK OR CASH BASED AWARDS; DIVIDEND EQUIVALENTS**

7.1 Other Stock or Cash Based Awards. Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will 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. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines.

7.2 Dividend Equivalents. A grant of Restricted Stock Units or Other Stock or Cash Based Award may provide a Participant with the right to receive Dividend Equivalents, and no Dividend Equivalents shall be payable with respect to Options or Stock Appreciation Rights. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Award with to which the Dividend Equivalents are paid and subject to other terms and conditions as set forth in the Award Agreement. Notwithstanding anything to the contrary herein, Dividend Equivalents with respect to an Award shall only paid out to the Participant to the extent that the vesting conditions are subsequently satisfied. All such Dividend Equivalent payments will be made no later than March 15 of the calendar year following calendar year in which the right to the Dividend Equivalent payment becomes nonforfeitable, unless determined otherwise by the Administrator or unless deferred in a manner intended to comply with Section 409A.

**ARTICLE VIII.  
ADJUSTMENTS FOR CHANGES IN COMMON STOCK  
AND CERTAIN OTHER EVENTS**

8.1 Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Article VIII, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants, and making a cash payment to Participants. The adjustments provided under this Section 8.1 will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

8.2 Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

(a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all Shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(c) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;

(d) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article IV on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price or applicable performance goals), and the criteria included in, outstanding Awards;

(e) To replace such Award with other rights or property selected by the Administrator; and/or

(f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

### 8.3 Effect of Non-Assumption in a Change in Control.

(a) Notwithstanding the provisions of Section 8.2, if a Change in Control occurs and a Participant's Awards are not continued, converted, assumed, or replaced with a substantially similar award by (a) the Company, or (b) a successor entity or its parent or subsidiary (an "**Assumption**"), and provided that the Participant has not had a Termination of Service, then, immediately prior to the Change in Control, such Awards shall become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions on such Awards shall lapse, in which case, such Awards shall be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Common Stock (i) which may be on such terms and conditions as apply generally to holders of Common Stock under the Change in Control documents (including, without limitation, any escrow, earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and (ii) determined by reference to the number of Shares subject to such Awards and net of any applicable exercise price; provided that to the extent that any Awards constitute "nonqualified deferred compensation" that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents); and provided, further, that if the amount to which the Participant would be entitled upon the settlement or exercise of such Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. The Administrator shall determine whether an Assumption of an Award has occurred in connection with a Change in Control.

(b) If a Change in Control occurs and a Participant's Awards have been assumed pursuant to Section 8.3(a), and if, on or within 12 months following such Change in Control, the Company or its successor entity or a parent or subsidiary thereof terminates such Participant's employment or service with such entity for any reason (other than for Cause and other than as a result of such Participant's death or Disability), then (A) such Participant's remaining unvested Awards (including any Substitute Awards) shall become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other

restrictions on such Awards (including any Substitute Awards) shall lapse, on the date of such Termination of Service, and (B) with respect to Options then held by such Participant, the Participant shall have a period of six months following the date of such Termination of Service (or such longer period as may be set forth in the applicable Award Agreement(s)) to exercise such Options, to the extent that he or she was otherwise entitled to exercise such Options on the date of such Termination of Service.

8.4 Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock, including any Equity Restructuring or any securities offering or other similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to 60 days before or after such transaction.

8.5 General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 8.1 or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Article VIII.

#### **ARTICLE IX. GENERAL PROVISIONS APPLICABLE TO AWARDS**

9.1 Transferability. Except as the Administrator may determine or provide in an Award Agreement or otherwise for Awards other than Incentive Stock Options, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except for certain beneficiary designations, by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, and, during the life of the Participant, will be exercisable only by the Participant. Any permitted transfer of an Award hereunder shall be without consideration, except as required by Applicable Law. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.

9.2 Documentation. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. The Award Agreement will contain the terms and conditions applicable to an Award. Each Award may contain terms and conditions in addition to those set forth in the Plan.

9.3 Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

9.4 Termination of Status. The Administrator will determine how the disability, death, retirement, an authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

9.5 Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by Applicable Law to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations based on the applicable statutory withholding rates (or such other rate as may be determined by the Company after considering any accounting consequences or costs) from any payment of any kind otherwise due to a Participant. In the absence of a contrary determination by the Company (or, with respect to withholding pursuant to clause (ii) below with respect to Awards held by individuals subject to Section 16 of the Exchange Act, a contrary determination by the Administrator), all tax withholding obligations will be calculated based on the maximum applicable statutory withholding rates. Subject to Section 10.8 and any Company insider trading policy (including blackout periods), Participants may satisfy such tax obligations (i) in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, provided that the Company may limit the use of the foregoing payment forms if one or more of the payment forms below is permitted, (ii) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares delivered by attestation and Shares retained from the Award creating the tax obligation, valued at their Fair Market Value on the date of delivery, (iii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iv) to the extent permitted by the Company, any combination of the foregoing payment forms approved by the Administrator. Notwithstanding any other provision of the Plan, the number of Shares which may be so delivered or retained pursuant to clause (ii) of the immediately preceding sentence shall be limited to the number of Shares which have a Fair Market Value on the date of delivery or retention no greater than the aggregate amount of such liabilities based on the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America); provided, however, to the extent such Shares were acquired by Participant from the Company as compensation, the Shares must have been held for the minimum period required by applicable accounting rules to avoid a charge to the Company's earnings for financial reporting purposes; provided, further, that, any such Shares delivered or retained shall be rounded up to the nearest whole Share to the extent rounding up to the nearest whole Share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America. If any tax withholding obligation will be satisfied under clause (ii) above by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

9.6 Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action will be required unless (i) the action, taking into account any related



action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Article VIII or pursuant to Section 10.6. Notwithstanding the foregoing or anything in the Plan to the contrary, the Administrator may, without the approval of the stockholders of the Company, (i) reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or (ii) cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights.

9.7 Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

9.8 Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

9.9 Cash Settlement. Without limiting the generality of any other provision of the Plan, the Administrator may provide, in an Award Agreement or subsequent to the grant of an Award, in its discretion, that any Award may be settled in cash, Shares or a combination thereof.

9.10 Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 9.5: (i) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (ii) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (iii) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (iv) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (v) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (vi) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

## **ARTICLE X. MISCELLANEOUS**

10.1 No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company or any of its Subsidiaries. The Company and its Subsidiaries expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement or in the Plan.

10.2 No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.

10.3 Effective Date and Term of Plan. Unless earlier terminated by the Board, the Plan will become effective on the day prior to the Public Trading Date (the "**Effective Date**") and will remain in effect until the tenth anniversary of the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's stockholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan. Notwithstanding anything to the contrary in the Plan, an Incentive Stock Option may not be granted under the Plan after 10 years from the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's stockholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan. If the Plan is not approved by the Company's stockholders, the Plan will not become effective, no Awards will be granted under the Plan and the Prior Plan will continue in full force and effect in accordance with its terms.

10.4 Amendment of Plan. The Board may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. No Awards may be granted under the Plan during any suspension period or after the Plan's termination. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

10.5 Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

#### 10.6 Section 409A.

(a) General. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 10.6 or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(b) Separation from Service. If an Award constitutes “nonqualified deferred compensation” under Section 409A, any payment or settlement of such Award upon a termination of a Participant’s Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant’s “separation from service” (within the meaning of Section 409A), whether such “separation from service” occurs upon or after the termination of the Participant’s Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a “termination,” “termination of employment” or like terms means a “separation from service.”

(c) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of “nonqualified deferred compensation” required to be made under an Award to a “specified employee” (as defined under Section 409A and as the Administrator determines) due to his or her “separation from service” will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such “separation from service” (or, if earlier, until the specified employee’s death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of “nonqualified deferred compensation” under such Award payable more than six months following the Participant’s “separation from service” will be paid at the time or times the payments are otherwise scheduled to be made.

10.7 Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan’s administration or interpretation, against any cost or expense (including attorneys’ fees) or liability (including any sum paid in settlement of a claim with the Administrator’s approval) arising from any act or omission concerning this Plan unless arising from such person’s own fraud or bad faith.

10.8 Lock-Up Period. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to 180 days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

10.9 Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant’s participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant’s name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the “**Data**”). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant’s participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant’s country, or elsewhere, and the Participant’s country may have different data privacy laws and protections

than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 10.9 in writing, without cost, by contacting the local human resources representative. If the Participant refuses or withdraws the consents in this Section 10.9, the Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards. For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

10.10 Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

10.11 Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.

10.12 Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding any state's choice-of-law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

10.13 Claw-back Provisions. All Awards (including, without limitation, any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as and to the extent set forth in such claw-back policy or the Award Agreement.

10.14 Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

10.15 Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.

10.16 Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

**ARTICLE XI.  
DEFINITIONS**

As used in the Plan, the following words and phrases will have the following meanings:

11.1 “**Administrator**” means the Board or a Committee to the extent that the Board’s powers or authority under the Plan have been delegated to such Committee.

11.2 “**Applicable Laws**” means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted.

11.3 “**Award**” means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Dividend Equivalents, or Other Stock or Cash Based Awards.

11.4 “**Award Agreement**” means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

11.5 “**Board**” means the Board of Directors of the Company.

11.6 “**Cause**” means, unless the applicable Award Agreement states otherwise, (i) “Cause” as defined in any employment or consulting agreement or similar services agreement between the Participant and the Company or an affiliate thereof as in effect at the time or, in the absence of any such employment, consulting, or similar services agreement (or the absence of any definition of “Cause” contained therein), (ii) the Participant’s (A) material breach of his or her obligations under any agreement or arrangement entered into with the Company or its affiliates (which remains uncured (to the extent the Committee reasonably determines curable) for at least ten (10) business days following notice of such breach); (B) gross negligence or willful misconduct in the performance of or non-performance of his or her duties to the Company or its affiliates; (C) breach of any of the Company’s or its affiliates’ written policies or procedures in each case in any respect which causes or is reasonably expected to cause harm to the Company or any affiliate thereof; (D) commission of a felony or a crime of moral turpitude (or the procedural equivalent of the foregoing); (E) commission of an act involving deceit, fraud, perjury or embezzlement involving the Company or its affiliates or any client, customer, supplier or business relationship of the Company or any affiliate thereof; (F) repeatedly being under the influence of drugs or alcohol (other than over-the-counter or prescription medicine or other medically related drugs to the extent they are taken in accordance with their directions or under the supervision of a physician) which inhibits the performance of such Participant’s duties to the Company or its affiliates, or, while under the influence of such drugs or alcohol, engaging in inappropriate conduct during the performance of his or her duties to the Company or its affiliates; or (G) failure to follow lawful directives of the Participant’s supervisor, which (which failure remains uncured (to the extent the Committee reasonably determines curable) for at least ten (10) business days following initial notice of such failure). Any rights to cure that are expressly described in this definition will only be afforded for the initial occurrence of any purported grounds of Cause and the Participant will not have any right (unless otherwise provided herein or unless the Administrator otherwise determines) to cure such purported grounds.

11.7 “**Change in Control**” means and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company’s assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company’s voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company’s assets or otherwise succeeds to the business of the Company (the Company or such person, the “**Successor Entity**”)) directly or indirectly, at least a majority of the combined voting power of the Successor Entity’s outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b) or (c) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a “change in control event,” as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

- 11.8 “**Code**” means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.
- 11.9 “**Committee**” means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a “non-employee director” within the meaning of Rule 16b-3; however, a Committee member’s failure to qualify as a “non-employee director” within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.
- 11.10 “**Common Stock**” means the common stock of the Company.
- 11.11 “**Company**” means Harmony Biosciences Holdings, Inc., a Delaware corporation, or any successor.
- 11.12 “**Consultant**” means any person, including any adviser, engaged by the Company or any of its Subsidiaries to render services to such entity if the consultant or adviser: (a) renders bona fide services to the Company; (b) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company’s securities; and (c) is a natural person.
- 11.13 “**Designated Beneficiary**” means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant’s rights if the Participant dies or becomes incapacitated. Without a Participant’s effective designation, “Designated Beneficiary” will mean the Participant’s estate.
- 11.14 “**Director**” means a Board member.
- 11.15 “**Disability**” means a permanent and total disability under Section 22(e)(3) of the Code, as amended.
- 11.16 “**Dividend Equivalent**” means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.
- 11.17 “**Employee**” means any employee of the Company or its Subsidiaries.
- 11.18 “**Equity Restructuring**” means, as determined by the Administrator, a non-reciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, or other large, nonrecurring cash dividend, that affects the Shares (or other securities of the Company) or the share price of Common Stock (or other securities of the Company) and causes a change in the per share value of the Common Stock underlying outstanding Awards.
- 11.19 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

11.20 “**Fair Market Value**” means, as of any date, the value of a share of Common Stock determined as follows: (a) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (b) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (c) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion.

Notwithstanding the foregoing, with respect to any Award granted on the pricing date of the Company’s initial public offering, the Fair Market Value shall mean the initial public offering price of a Share as set forth in the Company’s final prospectus relating to its initial public offering filed with the Securities and Exchange Commission.

11.21 “**Greater Than 10% Stockholder**” means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporation, as defined in Section 424(e) and (f) of the Code, respectively.

11.22 “**Incentive Stock Option**” means an Option intended to qualify as an “incentive stock option” as defined in Section 422 of the Code.

11.23 “**Non-Qualified Stock Option**” means an Option, or portion thereof, not intended or not qualifying as an Incentive Stock Option.

11.24 “**Option**” means an option to purchase Shares, which will either be an Incentive Stock Option or a Non-Qualified Stock Option.

11.25 “**Other Stock or Cash Based Awards**” means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property awarded to a Participant under Article VII.

11.26 “**Overall Share Limit**” means the sum of (a) 6,298,054 Shares; (b) any Shares which are subject to Prior Plan Awards as of the Effective Date which, following the Effective Date, become available for issuance under the Plan pursuant to Article IV (which number added to the Overall Share Limit shall not exceed [ • ] Shares); and (c) 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 lesser of (i) 4% of the aggregate number of Shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of Shares as is determined by the Board.

11.27 “**Participant**” means a Service Provider who has been granted an Award.

11.28 “**Performance Criteria**” means the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include but is not limited to: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return



on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends), including equity value or enterprise value; regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the Company's performance or the performance of a Subsidiary, division, business segment or business unit of the Company or a Subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

11.29 "**Plan**" means this 2020 Incentive Award Plan.

11.30 "**Prior Plan**" means the Harmony Biosciences Holdings, Inc. Amended and Restated Equity Incentive Plan, as amended.

11.31 "**Prior Plan Award**" means an award outstanding under the Prior Plan as of the Effective Date.

11.32 "**Public Trading Date**" means the first date upon which the Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a "publicly held corporation" for purposes of Treasury Regulation Section 1.162-27(c)(1).

11.33 "**Restricted Stock**" means Shares awarded to a Participant under Article VI subject to certain vesting conditions and other restrictions.

11.34 "**Restricted Stock Unit**" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date awarded to a Participant under Article VI subject to certain vesting conditions and other restrictions.

11.35 "**Rule 16b-3**" means Rule 16b-3 promulgated under the Exchange Act.

11.36 "**Section 409A**" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

11.37 "**Securities Act**" means the Securities Act of 1933, as amended.

11.38 "**Service Provider**" means an Employee, Consultant or Director.

11.39 "**Shares**" means shares of Common Stock.

11.40 "**Stock Appreciation Right**" means a stock appreciation right granted under Article V.

11.41 “**Subsidiary**” means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

11.42 “**Substitute Awards**” means Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

11.43 “**Termination of Service**” means the date the Participant ceases to be a Service Provider.

\* \* \* \* \*

## HARMONY BIOSCIENCES HOLDINGS, INC.

## FORM OF STOCK OPTION AGREEMENT

Harmony Biosciences Holdings, Inc., a Delaware corporation (the “**Company**”), is pleased to advise you, the “**Participant**” whose signature appears on the signature page hereto, that the Company has granted to you a stock option (an “**Option**”), as provided below, under the Company’s “Harmony Biosciences Holdings, Inc. Amended and Restated Equity Incentive Plan” (as amended from time to time, the “**Plan**”), a copy of which is attached hereto and incorporated herein by reference. The Option has been granted, and the shares of Common Stock issuable upon exercise will be issued, pursuant to a “compensatory benefit plan” within the meaning of such term under Rule 701 of the Exchange Act.

**Participant Name:** \_\_\_\_\_

**Address on file with Company**

You have been granted an Option to purchase shares of Common Stock of the Company, subject to the terms and conditions of the Plan and this Stock Option Agreement, as follows:

Date of Grant: \_\_\_\_\_

Commencement Date: \_\_\_\_\_

Exercise Price per Share: \$ \_\_\_\_\_

Total # of Shares subject to Option: \_\_\_\_\_

Total Exercise Price: \_\_\_\_\_

Type of Option: \_\_\_\_\_ Incentive Stock Option

\_\_\_\_\_ Nonstatutory Stock Option

Expiration Date: \_\_\_\_\_

1. Definitions. Capitalized terms used but not defined in this Stock Option Agreement (this “**Agreement**”) shall have the meanings set forth in the Plan.

2. Option.

(a) This Option entitles you to purchase up to the number of shares of Common Stock set forth on the first page of this Agreement at an exercise price per share (the “**Exercise Price**”) as set forth on the first page of this Agreement. Your Option shall expire at the close of business on the expiration date set forth on the first page of this Agreement (the “**Expiration Date**”), subject to earlier expiration as provided in Section 3 below. Your Option is not intended to be an “incentive stock option” within the meaning of Section 422 of the Code.

(b) Payment of Option Price. Subject to Section 3 below, your Option may be exercised in whole or in part upon payment of an amount (the “**Option Price**”) equal to the product of (i) the Exercise Price multiplied by (ii) the number of shares of Common Stock to be acquired, unless otherwise determined by the Committee. Payment of the Exercise Price shall be by any of the following, or a combination of the following, at your election: (A) cash or check; (B) at the discretion of the Committee on a case by case basis, by surrender of other shares of Common Stock of the Company that have an aggregate Fair Market Value on the date of surrender equal to the aggregate Exercise Price of the shares as to which this Option is being exercised; or (C) at the discretion of the Committee on a case by case basis, by a cashless exercise or promissory note program approved by the Committee.

3. Vesting; Expiration; Exercisability.

(a) Vesting. Your Option may be exercised only to the extent it has become vested. Subject to your continued employment or engagement by the Company or an Affiliate on each applicable vesting date, and except as may otherwise be provided herein or in the Plan, twenty percent (20%) of the Option shall become vested on the first anniversary of the Commencement Date (the “*First Vesting Date*”), and the remaining eighty percent (80%) shall become vested ratably on each of the subsequent four anniversaries following the First Vesting Date. The Option shall not vest at any time after the termination of your employment or engagement with the Company.

(b) Change in Control. Notwithstanding anything to the contrary herein, upon the occurrence of a Change in Control, and irrespective of whether outstanding Options are being assumed, substituted, exchanged or terminated in connection with the transaction, the vesting of your Option shall accelerate such that all unvested Options shall become exercisable and vested to the extent not then otherwise vested. The portion of your Option that has not yet become vested shall become vested as provided herein due to a Change in Control if and only if, as of the date of the consummation of such Change in Control, you remain employed or engaged by the Company or an Affiliate from the Commencement Date through and including such Change in Control. In any event, any portion of your Option which has not been exercised prior to or in connection with the Change in Control shall expire and be forfeited for no consideration, unless otherwise determined by the Committee.

(c) Expiration of Option. In no event shall any part of your Option be exercisable after the Expiration Date.

(d) Early Expiration upon Termination of Employment. Except as otherwise provided in Section 4(a)(iii) of the Plan, any portion of your Option that was not vested and exercisable as of the date on which your employment or service with the Company or an Affiliate terminates shall expire and be forfeited on such date, and any portion of your Option that was vested and exercisable as of such termination date shall also expire and be forfeited as of such termination date.

(e) Procedure for Exercise. You may exercise all or any portion of your Option, to the extent it has vested and is exercisable, at any time and from time to time prior to its expiration, by delivering to the Company's Corporate Secretary an Exercise Notice in the form attached to this Agreement as Exhibit A, and a duly executed joinder, in form and content acceptable to the Company, to all or portions of any stockholders, financing, or other agreement as determined by the Committee, together with payment of the Option Price in accordance with the provisions of Section 2(b) above. As a condition to any exercise of your Option, you shall make all customary investment representations which the Company requires. The Company is not obligated, and will have no liability for failure, to issue or deliver any shares of Common Stock upon exercise of this Option unless such issuance or delivery would comply with applicable laws, with such compliance determined by the Company in consultation with its legal counsel. As a condition to the exercise of your Option, and as further set forth in Section 6 of this Agreement, you agree to make adequate provision, acceptable to the Company, for federal, state, local and non-U.S. income an employment tax withholding obligations, if any, which arise upon the grant, vesting or exercise of this Option, or disposition of shares of Common Stock acquired upon exercise of this Option, whether by withholding, direct payment to the Company, or otherwise. Further, if you (or any other person) is exercising this Option in connection with or following the Company's termination of your employment or engagement with the Company or an Affiliate, as a condition to exercise of your Option and the issuance of shares of Common Stock hereunder, you shall execute and deliver to the Company a general release of claims with respect to the termination of your employment or engagement with the Company or any Affiliate in form and substance provided to you by the Company at that time.

4. Conformity with Plan. Your Option is intended to conform in all respects with, and is subject to all applicable provisions of, the Plan (which is incorporated herein by reference). Inconsistencies between this Option and the Plan shall be resolved in accordance with the terms of the Plan. By executing and returning the enclosed copy of this Option, you acknowledge your receipt of this Option and the Plan and agree to be bound by all of the terms of this Option and the Plan.

5. Rights of Participants. Nothing in this Option shall interfere with or limit in any way the right of the Company or any of its Affiliates to terminate your employment or engagement at any time (with or without Cause), nor confer upon you any right to continue to be employed or engaged by the Company or any Affiliate for any period of time or to continue your present (or any other) rate of compensation or benefits. In the event of any termination of your employment or engagement with the Company or an Affiliate (including any termination of your employment or engagement by the Company or an Affiliate without Cause), any portion of your Option that was not previously vested and exercisable shall expire and be forfeited, except as otherwise provided herein or in the Plan. Nothing in this Option shall confer upon you any right to be selected again as a participant under the Plan, and nothing in the Plan or this Option shall provide for any adjustment to the number of shares of Common Stock subject to your Option upon the occurrence of subsequent events, except as provided in Section 7 or the Plan. Also, to the extent applicable, the Exercise Price has been set in good faith compliance with the applicable guidance issued by the IRS under Section 409A of the Internal Revenue Code of 1986, as amended. However, there is no guarantee that the IRS will agree with the valuation, and by signing below, you agree and acknowledge that the Company shall not be held liable for any applicable costs, taxes or penalties associated with this Option if, in fact, the IRS were to determine that this Option constitutes deferred compensation under Section 409A of the Code. You should consult with your own tax advisor concerning the tax consequences of such a determination by the IRS.

6. Withholding of Taxes. The Company shall be entitled, if necessary or desirable, to deduct and withhold from you, from any amounts due and payable by the Company to you (or secure payment from you in lieu of withholding), the amount of any withholding or other tax due in connection with the issuance, vesting, ownership, modification, adjustment, disposition, exercise or otherwise with respect to your Option or the securities issuable under your Option, and the Company may defer the issuance

of shares of Common Stock under your Option unless you make arrangements satisfactory to the Company for your payment of such amounts or indemnification of the Company with respect to such matters. In the event that the Company does not make such deductions or withholdings, you shall indemnify the Company for and remain responsible for any amounts paid or payable by the Company with respect to any such taxes, together with any interest, penalties and additions to tax and any related expenses thereto.

7. Adjustments. In the event of a reorganization, recapitalization, stock dividend or stock split, or combination or other change in the shares of Common Stock, the Committee shall make such adjustments in the number and type of securities authorized by the Plan, the number and type of securities covered by your Option and the Exercise Price specified herein as the Committee may determine to be appropriate and equitable.

8. Miscellaneous.

(a) Amendment. Except as otherwise provided herein, any provision of this Agreement may be amended or waived only with the prior written consent of you and the Company. This Agreement may also be amended as provided under the Plan, but no such amendment shall adversely effect your rights under this Agreement without your written consent, unless otherwise permitted by the Plan.

(b) Successors and Assigns. Except as otherwise expressly provided herein, all covenants and agreements contained in this Agreement by or on behalf of any of the parties hereto shall bind and inure to the benefit of the respective successors and permitted assigns of the parties hereto whether so expressed or not.

(c) Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

(d) Counterparts and Delivery by Facsimile or Email. This Agreement and any agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement, and, to the extent signed and delivered by means of a facsimile machine or email (including by an attachment thereto (e.g., PDF)), shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto shall re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument shall raise the use of a facsimile machine or email (including by an attachment thereto (e.g., PDF)) to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of a facsimile machine or by email as a defense to the formation of a contract and each such party forever waives any such defense.

(e) No Strict Construction. The language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any party.

(f) Construction; Determinations. This Agreement is granted pursuant to the Plan and is, in all respects, limited by and subject to the express provisions of the Plan, as amended from time to time. The interpretation and construction by the Committee of the Plan, this Agreement and any such rules and regulations adopted by the Committee for purposes of administering the Plan, shall be final, conclusive

and binding upon you and all other Persons. The descriptive headings of the sections of this Agreement are for convenience only and do not constitute a part of this Agreement. The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter for Ms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. Unless the context requires otherwise (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (ii) any reference herein to any Person shall be construed to include such Person’s successors and assigns, (iii) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof and (iv) all references herein to sections shall be construed to refer to sections of this Agreement unless otherwise noted.

(g) Governing Law. Any issues, disputes or claims arising out of or in connection with this Agreement and all issues and questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed in accordance with the laws 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.

(h) Notices. Any communication or notice required or permitted to be given hereunder shall be in writing, and, if to the Company, to its principal place of business, attention: Chief Executive Officer, and, if to you, to the address appearing on the records of the Company. Such communication or notice shall be delivered personally or by a reputable overnight delivery service. Any such notice shall be deemed given when received by the intended recipient. Notwithstanding the foregoing, any notice required or permitted hereunder from the Company to you may be made by electronic means, including by electronic mail to your Company-maintained electronic mailbox, and you hereby consent to receive such notice by electronic delivery. To the extent permitted in an electronically delivered notice described in the previous sentence, you shall be permitted to respond to such notice or communication by way of a responsive electronic communication, including by electronic mail.

(i) Waiver of Section 220 of the DGCL. You acknowledge and understand that, but for the waiver made herein, you would be entitled, upon written demand under oath stating the purpose thereof, to inspect for any proper purpose, and to make copies and extracts from, the Company’s stock ledger, a list of its stockholders, and its other books and records, and the books and records of subsidiaries of the Company, if any, under the circumstances and in the manner provided in Section 220 of the General Corporation Law of Delaware (any and all such rights, and any and all such other rights of yours as may be provided for in Section 220, the “**Inspection Rights**”). In light of the foregoing, until the first sale of Common Stock of the Company to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Exchange Act, you hereby unconditionally and irrevocably waive the Inspection Rights, whether such Inspection Rights would be exercised or pursued directly or indirectly pursuant to Section 220 or otherwise, and covenants and agrees never to directly or indirectly commence, voluntarily aid in any way, prosecute, assign, transfer, or cause to be commenced any claim, action, cause of action, or other proceeding to pursue or exercise the Inspection Rights.

(j) Restrictive Covenants. As a condition to this Agreement and to eligibility, receipt or retention of the payments, rights and benefits in respect of the Options awarded hereunder, you agree to those additional terms set forth on Exhibit B, which are hereby incorporated by reference and which shall survive termination of your service or employment with the Company or any Affiliates

(k) WAIVER OF JURY TRIAL; JURISDICTION. NO PARTY TO THIS AGREEMENT OR ANY ASSIGNEE, SUCCESSOR, HEIR OR PERSONAL REPRESENTATIVE OF A PARTY SHALL SEEK A JURY TRIAL IN ANY LAWSUIT, PROCEEDING, COUNTERCLAIM OR ANY OTHER LITIGATION PROCEDURE BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY OF THE OTHER AGREEMENTS OR THE DEALINGS OR THE RELATIONSHIP BETWEEN THE PARTIES. NO PARTY WILL SEEK TO CONSOLIDATE ANY SUCH ACTION, IN WHICH A JURY TRIAL HAS BEEN WAIVED, WITH ANY OTHER ACTION IN WHICH A JURY TRIAL CANNOT OR HAS NOT BEEN WAIVED. THE PROVISIONS OF THIS PARAGRAPH HAVE BEEN FULLY DISCUSSED BY THE PARTIES HERETO, AND THESE PROVISIONS SHALL BE SUBJECT TO NO EXCEPTIONS. THE PARTIES AGREE THAT ANY ACTIONS OR PROCEEDINGS ARISING IN CONNECTION WITH THIS AGREEMENT SHALL BE TRIED AND LITIGATED EXCLUSIVELY IN THE FEDERAL OR STATE COURTS LOCATED IN COOK COUNTY, ILLINOIS. NEITHER PARTY HAS IN ANY WAY AGREED WITH OR REPRESENTED TO ANY OTHER PARTY THAT THE PROVISIONS OF THIS PARAGRAPH WILL NOT BE FULLY ENFORCED IN ALL INSTANCES.

(l) Entire Agreement. This Agreement and the Plan constitute the entire understanding between you and the Company and supersede all other agreements, whether written or oral, with respect to the acquisition by you of Common Stock of the Company.

\* \* \* \* \*



Please execute the extra copy of this Agreement in the space below and return it to the Company's at its executive offices to confirm your understanding and acceptance of the agreements contained in this Agreement.

Very truly yours,

**HARMONY BIOSCIENCES HOLDINGS, INC.**

By: \_\_\_\_\_

Its: General Counsel \_\_\_\_\_

The undersigned hereby acknowledges having read this Agreement and the Plan and hereby agrees to be bound by all provisions set forth herein and in the Plan.

PARTICIPANT

Name: \_\_\_\_\_

**EXHIBIT A**  
OPTION EXERCISE NOTICE

The undersigned is the holder of an option (the “**Option**”) to acquire [number of options in grant] shares of Common Stock in Harmony Biosciences Holdings, Inc. (the “**Company**”) granted pursuant to that certain Stock Option Agreement, dated as of [Grant Date] (the “**Stock Option Agreement**”). Capitalized terms used and not otherwise defined in this option exercise notice shall have the meaning given to such terms in the Plan. Subject to the further conditions of Section 3(d) of the Stock Option Agreement, the undersigned hereby exercises the Option with respect to \_\_\_\_\_ shares of Common Stock for an aggregate exercise price of \$\_\_\_\_\_, payable in accordance Section 2(b) of the Stock Option Agreement.

In connection with the foregoing exercise of the Option, the undersigned represents and acknowledges to the Company as follows:

- 1) He or she has received a copy of the Plan and has read and understands the Plan.
- 2) He or she has executed a joinder to all stockholders, financing, and related agreements provided by the Company.
- 3) The shares of Common Stock are subject to transfer restrictions set forth in one or more stockholders’ agreements and are subject to repurchase pursuant to the terms of the Stock Option Agreement and/or Plan.
- 4) The shares of Common Stock have not been registered under the Exchange Act and are offered pursuant to an exemption thereunder and that such shares of Common Stock have not been approved or disapproved by the Securities and Exchange Commission or by any other Federal or state agency.
- 5) The shares of Common Stock acquired upon exercise of the Option are being acquired for investment purposes, and not on behalf or for the benefit of any other person, trust, estate or business organization, and the undersigned has no intention of distributing any shares of Common Stock to others in violation of the Exchange Act.
- 6) There are no existing circumstances which will compel the undersigned to obtain money by the sale of any shares of Common Stock, and the undersigned has no reason to anticipate any change in such undersigned’s circumstances, financial or otherwise, or to anticipate any occasion or event, which would cause the undersigned to assign, transfer, sell or distribute, or necessitate or require the undersigned to assign, transfer, sell or distribute, any shares of Common Stock. The undersigned understands that the shares of Common Stock are illiquid and that the undersigned may be required to hold the shares of Common Stock indefinitely.
- 7) The shares of Common Stock may also be subject to resale restrictions imposed by the securities laws of various states and may not be sold without compliance with such laws.
- 8) The undersigned is a resident of the State of [name of State].
- 9) The undersigned is responsible for the tax consequences relating to the exercise of the Option.

Executed this date of \_\_\_\_\_  
[participant name]

**EXHIBIT B**  
ADDITIONAL TERMS

(a) **Acknowledgements.** Capitalized terms used in this Exhibit B and not elsewhere defined in the Agreement to which this Exhibit B is attached shall have the meanings set forth in paragraph (j) of this Exhibit B. This Exhibit B is intended to apply **in addition to and not in lieu of** any similar covenant or term in Participant's employment or services agreement, offer letter or similar document or other arrangement with the Company or any of its Affiliates (the Company and its Affiliates are collectively referred to herein, the "**Company Group**"), and by signing the Agreement Participant acknowledges and agrees to same. Participant acknowledges that the Participant has been advised by the Company that the restrictions and covenants contained in this Exhibit B, and the Participant's agreement to such restrictions and covenants, constitute a material inducement to the Company to execute the Agreement, to provide the Participant with the Shares pursuant to the Agreement to which this Exhibit is attached. The Participant acknowledges that participation in the Plan and eligibility for such Shares constitutes sufficient consideration for the promises and agreements made by the Participant hereunder, which shall survive the termination of the Participant's employment or service with the Company Group. The Participant acknowledges that: (i) as a result of the Participant's employment or service with the Company Group, the Participant has obtained and will continue to obtain Confidential Information; (ii) the Confidential Information, and each element or aspect thereof, has been developed and created by the Company Group at substantial time and expense; (iii) the Confidential Information constitutes valuable proprietary assets of the Company Group, the Company Group's reservation of rights and control of Confidential Information is of significant competitive importance and commercial value to the Company Group, and the Company Group will suffer substantial damage and irreparable harm which will be difficult to compute if, during the period of employment or service or thereafter, the Participant discloses or improperly uses any such Confidential Information in violation of the provisions of this Exhibit B; (iv) the nature of the Company Group's business is such that it is highly competitive and could be conducted anywhere in the world and is not limited to any particular geographic scope or region(s); (v) the Company Group will suffer substantial damage and irreparable harm which will be difficult to compute if, during the period of employment or service or thereafter, the Participant should solicit or interfere with any individual employed by or providing services to any of the Company Group or their investment opportunities, acquisition targets, financing sources, suppliers or customers in violation of this Exhibit B; (vi) the provisions of this Exhibit B are reasonable and necessary for the protection of the legitimate business interests of the Company Group; (vii) the provisions of this Exhibit B will not preclude the Participant from other gainful employment or service following the termination of his or her services to the Company Group; (viii) the Confidential Information constitutes a protectable business interest of the Company Group; (ix) that Confidential Information is vital, sensitive, confidential and proprietary to the Company Group; and (x) a breach by the Participant of this Exhibit B would result in losses to the Company Group for which remedies at law are inadequate, and would result in the expenditure of additional financial costs, loss of business advantage and opportunities, potential liability under confidentiality obligations with third parties and potential civil and criminal penalties.

(b) **Obligation to Maintain Confidentiality.** The Participant acknowledges that the information, observations and data obtained by him during the course of his service with the Company concerning the business and affairs of the Company Group, including, but not limited to, information concerning acquisition opportunities in or reasonably related to the business of the Company Group ("**Confidential Information**"), of which Participant becomes aware during the Participant's service with the Company are the property of the Company Group. Therefore, Participant agrees that he will not disclose to any unauthorized Person or use for his own account any Confidential Information without the Board's written consent, unless and to the extent that the aforementioned matters (i) become generally known to and available for use by the public other than as a result of Participant's acts or omissions in breach of this Agreement, (ii) were known by Participant prior to his commencement of service with the Company (other than Confidential Information disclosed to Participant in confidence in connection with Participant's employment with Company or another member of the Company Group), or (iii) is required to be disclosed pursuant to any applicable law or court order. Participant agrees to deliver to Company upon Participant's termination of service with the Company, or at any other time Company may request in writing, all memoranda,

notes, plans, records, reports and other documents (and copies thereof) relating to the business of the Company Group (including, without limitation, all acquisition prospects, lists and contact information) or containing Confidential Information which he may then possess or have under his control.

(c) Third Party Information. Participant understands that the Company Group will receive from third parties confidential or proprietary information (“**Third Party Information**”) subject to a duty on the part of the Company Group to maintain the confidentiality of such information and to use it only for certain limited purposes. Participant will hold Third Party Information in strictest confidence and will not disclose to anyone (other than personnel, consultants, attorneys, accountants and other advisors of the Company Group who need to know such information in connection with their work for the Company Group) or use such Third Party Information, except to the extent that (i) such Third Party Information shall have become generally known to and available for use by the public other than as a result of Participant’s acts or omissions in breach of this Agreement, (ii) such Third Party Information is required to be disclosed pursuant to any applicable law or court order, or (iii) the disclosure of such Third Party Information is expressly authorized by the Board in writing.

(d) Noncompetition and Nonsolicitation. Participant acknowledges that in the course of his service with Company he will become familiar with trade secrets and other confidential information concerning the Company Group and that his services will be of special, unique and extraordinary value to Company. Therefore, Participant agrees that:

(i) Noncompetition. For a period of one year following the Participant’s service with the Company Group, Participant shall not, anywhere in the world, directly or indirectly own, manage, control, participate in, consult with, render services for, or in any manner engage in any business that is a Competing Business as of the relevant date of determination.

(ii) Nonsolicitation. For a period of one year following the Participant’s service with the Company Group, Participant shall not, other than in the good faith performance of his duties for the Company Group, directly or indirectly through another entity induce or attempt to induce any employee of the Company Group to leave the employ of any member of the Company Group.

(e) Relief. The Participant further acknowledges that the Company Group are third party beneficiaries of the Agreement and this Exhibit B and will be irreparably harmed if such covenants are not specifically enforced. Accordingly, Participant agrees that in addition to any other relief to which the Company Group may be entitled, in law or equity, they shall be entitled to obtain injunctive relief (without the requirement of posting a bond or other security) from a court of competent jurisdiction, for the purpose of restraining the Participant from an actual or threatened breach of any such covenants. Participant also acknowledges that the remedies afforded pursuant to this paragraph (i) are not exclusive, nor shall they preclude any member of the Company Group from seeking or receiving any other relief, including without limitation, any form of monetary or other equitable relief. Upon the reasonable request by any member of the Company Group, the Participant shall provide reasonable assurances and evidence of compliance with the terms of this Exhibit B. In the event that injunctive relief or specific enforcement of the Participant’s obligations hereunder is required, the Participant will (i) indemnify and hold the Company Group harmless with respect to any damages (whether actual or otherwise), actions, losses, costs and liabilities arising from the Participant’s breach of the Participant’s obligations under the Agreement or this Exhibit B, including providing an accounting (and provide such information as is reasonably necessary for the Company to create or confirm such accounting) and disgorging any profits, gains or other windfalls resulting directly or indirectly from such breach, and (ii) reimburse or pay on demand the Company Group, as applicable, for fees and costs incurred by them (including, without limitation, reasonable attorneys’ fees and costs) in obtaining such injunctive relief or specific enforcement and/or in seeking such damages.

(j) Definitions. For purposes of this Exhibit B, the following definitions are applicable:

“**Business**” means, at the relevant time, the licensing, acquisition, development, commercialization, distribution and lifecycle management of pharmaceutical products in those therapeutic areas in which the Company Group is materially engaged.

“**Competing Business**” means any business that competes with the Business.

(k) Judicial Modification. If any court shall deem any of the provisions of the Agreement or this Exhibit B invalid or unenforceable under any applicable law, by reason of being vague or unreasonable as to area, duration or scope of activity, it is the parties’ intentions and desire that such court shall have the authority to modify the Agreement and this Exhibit B and will so modify such Agreement and this Exhibit B in a manner so as to render it enforceable while maintaining the original intent thereof to the maximum extent possible. In the event of such modification, the Participant and the Company agrees that this Agreement and Exhibit B, as so amended, shall be valid and binding as though any invalid or unenforceable provision never had been included herein.

(l) Severability. If any term or provision shall be held invalid or unenforceable, the remaining terms and provisions hereof shall not be affected thereby, unless such a construction would be unreasonable.

\*\*\*

HARMONY BIOSCIENCES HOLDINGS, INC.

2020 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

Harmony Biosciences Holdings, Inc., a Delaware corporation (the "Company"), has granted to the participant listed below ("Participant") the Restricted Stock Units (the "RSUs") described in this Restricted Stock Unit Grant Notice (this "Grant Notice"), subject to the terms and conditions of the Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan (as amended from time to time, the "Plan") and the Restricted Stock Unit Agreement attached hereto as Exhibit A (the "Agreement"), both of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:

Grant Date:

Number of RSUs:

Vesting Commencement Date:

Vesting Schedule: [To be specified]

By accepting (whether in writing, electronically or otherwise) the RSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

HARMONY BIOSCIENCES HOLDINGS, INC.

PARTICIPANT

By: \_\_\_\_\_

\_\_\_\_\_

Name: \_\_\_\_\_

[Participant Name]

Title: \_\_\_\_\_

**RESTRICTED STOCK UNIT AGREEMENT**

Capitalized terms not specifically defined in this Restricted Stock Unit Agreement (this “**Agreement**”) have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE I.  
GENERAL**

1.1 **Award of RSUs.** The Company has granted the RSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the “**Grant Date**”). Each RSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the RSUs have vested.

1.2 **Incorporation of Terms of Plan.** The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 **Unsecured Promise.** The RSUs will at all times prior to settlement represent an unsecured Company obligation payable only from the Company’s general assets.

**ARTICLE II.  
VESTING; FORFEITURE AND SETTLEMENT**

2.1 **Vesting; Forfeiture.** The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant’s Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company.

2.2 **Settlement.**

(a) The RSUs will be paid in Shares as soon as administratively practicable after the vesting of the applicable RSU, but in no event later than March 15 of the year following the year in which the RSU’s vesting date occurs.

(b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

**ARTICLE III.  
TAXATION AND TAX WITHHOLDING**

3.1 **Representation.** Participant represents to the Company that Participant has reviewed with Participant’s own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

### 3.2 Tax Withholding.

(a) Unless the Administrator otherwise determines, the Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award (including the RSUs) in satisfaction of any applicable withholding tax obligations. The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a Fair Market Value on the date of withholding no greater than the aggregate amount of such liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and its Subsidiaries do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

## **ARTICLE IV. OTHER PROVISIONS**

4.1 Adjustments. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the Designated Beneficiary) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.



4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the RSUs will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

\* \* \* \* \*

## HARMONY BIOSCIENCES HOLDINGS, INC.

## 2020 EMPLOYEE STOCK PURCHASE PLAN

ARTICLE I.  
PURPOSE

The purposes of this Harmony Biosciences Holdings, Inc. 2020 Employee Stock Purchase Plan (as it may be amended or restated from time to time, the “**Plan**”) are to assist Eligible Employees of Harmony Biosciences Holdings, Inc., a Delaware corporation (the “**Company**”), and its Designated Subsidiaries in acquiring a stock ownership interest in the Company pursuant to a plan which is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423(b) of the Code, and to help Eligible Employees provide for their future security and to encourage them to remain in the employment of the Company and its Designated Subsidiaries.

ARTICLE II.  
DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates. Masculine, feminine and neuter pronouns are used interchangeably and each comprehends the others.

2.1 “**Administrator**” shall mean the entity that conducts the general administration of the Plan as provided in Article XI. The term “Administrator” shall refer to the Committee unless the Board has assumed the authority for administration of the Plan as provided in Article XI.

2.2 “**Applicable Law**” shall mean the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where rights under this Plan are granted.

2.3 “**Board**” shall mean the Board of Directors of the Company.

2.4 “**Change in Control**” shall mean and include each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new director(s) of the Company (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "**Successor Entity**") directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any portion of any right that constitutes "nonqualified deferred compensation," the transaction or event constituting the Change in Control with respect to such right (or portion thereof) must also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) to trigger the payment event for such right, to the extent required by Section 409A of the Code. The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.5 "**Code**" shall mean the Internal Revenue Code of 1986, as amended and the regulations issued thereunder.

2.6 "**Common Stock**" shall mean the common stock of the Company and such other securities of the Company that may be substituted therefor pursuant to Article VIII.

2.7 "**Company**" shall mean Harmony Biosciences Holdings, Inc., a Delaware corporation.

2.8 "**Compensation**" of an Eligible Employee shall mean the gross cash compensation received by such Eligible Employee as compensation for services to the Company or any Designated Subsidiary, including prior week adjustment and overtime payments but excluding commissions and periodic bonuses, vacation pay, holiday pay, jury duty pay, funeral leave pay, military leave pay, one-time bonuses (e.g., retention or sign on bonuses), education or tuition reimbursements, travel expenses,

business and moving reimbursements, income received in connection with any stock options, stock appreciation rights, restricted stock, restricted stock units or other compensatory equity awards, fringe benefits, other special payments and all contributions made by the Company or any Designated Subsidiary for the Employee's benefit under any employee benefit plan now or hereafter established.

2.9 "**Designated Subsidiary**" shall mean any Subsidiary designated by the Administrator in accordance with Section 11.3(b).

2.10 "**Effective Date**" shall mean the day prior to the Public Trading Date, provided that the Board has adopted the Plan prior to or on such date.

2.11 "**Eligible Employee**" shall mean an Employee who does not, immediately after any rights under this Plan are granted, own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of Common Stock and other stock of the Company, a Parent or a Subsidiary (as determined under Section 423(b)(3) of the Code). For purposes of the foregoing sentence, the rules of Section 424(d) of the Code with regard to the attribution of stock ownership shall apply in determining the stock ownership of an individual, and stock that an Employee may purchase under outstanding options shall be treated as stock owned by the Employee; provided, however, that the Administrator may provide in an Offering Document that an Employee shall not be eligible to participate in an Offering Period if: (a) such Employee is a highly compensated employee within the meaning of Section 423(b)(4)(D) of the Code, (b) such Employee has not met a service requirement designated by the Administrator pursuant to Section 423(b)(4)(A) of the Code (which service requirement may not exceed two years), (c) such Employee's customary employment is for 20 hours or less per week, (d) such Employee's customary employment is for less than five months in any calendar year and/or (e) such Employee is a citizen or resident of a foreign jurisdiction and the grant of a right to purchase Common Stock under the Plan to such Employee would be prohibited under the laws of such foreign jurisdiction or the grant of a right to purchase Common Stock under the Plan to such Employee in compliance with the laws of such foreign jurisdiction would cause the Plan to violate the requirements of Section 423 of the Code, as determined by the Administrator in its sole discretion; provided, further, that any exclusion in clauses (a), (b), (c), (d) or (e) shall be applied in an identical manner under each Offering Period to all Employees, in accordance with Treasury Regulation Section 1.423-2(e).

2.12 "**Employee**" shall mean any officer or other employee (as defined in accordance with Section 3401(c) of the Code) of the Company or any Designated Subsidiary. "Employee" shall not include any director of the Company or a Designated Subsidiary who does not render services to the Company or a Designated Subsidiary as an employee within the meaning of Section 3401(c) of the Code. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on sick leave or other leave of absence approved by the Company or Designated Subsidiary and meeting the requirements of Treasury Regulation Section 1.421-1(h)(2). Where the period of leave exceeds three months and the individual's right to reemployment is not guaranteed either by statute or by contract, the employment relationship shall be deemed to have terminated on the first day immediately following such three-month period.

2.13 "**Enrollment Date**" shall mean the first Trading Day of each Offering Period.

2.14 "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.15 "**Fair Market Value**" shall mean, as of any date, the value of a share of Common Stock determined as follows: (a) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such

date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (b) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (c) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion.

2.16 “**Offering Document**” shall have the meaning given to such term in Section 4.1.

2.17 “**Offering Period**” shall have the meaning given to such term in Section 4.1.

2.18 “**Parent**” shall mean any corporation, other than the Company, in an unbroken chain of corporations ending with the Company if, at the time of the determination, each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

2.19 “**Participant**” shall mean any Eligible Employee who has executed a subscription agreement and been granted rights to purchase Common Stock pursuant to the Plan.

2.20 “**Plan**” shall mean this Harmony Biosciences Holdings, Inc. 2020 Employee Stock Purchase Plan, as it may be amended from time to time.

2.21 “**Public Trading Date**” shall mean the first date upon which the Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a “publicly held corporation” for purposes of Treasury Regulation Section 1.162-27(c)(1).

2.22 “**Purchase Date**” shall mean the last Trading Day of each Purchase Period.

2.23 “**Purchase Period**” shall refer to one or more periods within an Offering Period, as designated in the applicable Offering Document; provided, however, that, in the event no Purchase Period is designated by the Administrator in the applicable Offering Document, the Purchase Period for each Offering Period covered by such Offering Document shall be the same as the applicable Offering Period.

2.24 “**Purchase Price**” shall mean the purchase price designated by the Administrator in the applicable Offering Document (which purchase price shall not be less than 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower); provided, however, that, in the event no purchase price is designated by the Administrator in the applicable Offering Document, the purchase price for the Offering Periods covered by such Offering Document shall be 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower; provided, further, that the Purchase Price may be adjusted by the Administrator pursuant to Article VIII and shall not be less than the par value of a Share.

2.25 “**Securities Act**” shall mean the Securities Act of 1933, as amended.

2.26 “**Share**” shall mean a share of Common Stock.

2.27 “**Subsidiary**” shall mean any corporation, other than the Company, in an unbroken chain of corporations beginning with the Company if, at the time of the determination, each of the corporations other than the last corporation in an unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain; provided, however, that a limited liability company or partnership may be treated as a Subsidiary to the extent either (a) such entity is treated as a disregarded entity under Treasury Regulation Section 301.7701-3(a) by reason of the Company or any other Subsidiary that is a corporation being the sole owner of such entity, or (b) such entity elects to be classified as a corporation under Treasury Regulation Section 301.7701-3(a) and such entity would otherwise qualify as a Subsidiary.

2.28 “**Trading Day**” shall mean a day on which national stock exchanges in the United States are open for trading.

### **ARTICLE III. SHARES SUBJECT TO THE PLAN**

3.1 Number of Shares. Subject to Article VIII, the aggregate number of Shares that may be issued pursuant to rights granted under the Plan shall be 629,805 Shares. In addition to the foregoing, subject to Article VIII, on the first day of each calendar year beginning on January 1, 2021 and ending on and including January 1, 2030, the number of Shares available for issuance under the Plan shall be increased by that number of Shares equal to the lesser of (a) 1% of the Shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of Shares as determined by the Board. If any right granted under the Plan shall for any reason terminate without having been exercised, the Common Stock not purchased under such right shall again become available for issuance under the Plan. Notwithstanding anything in this Section 3.1 to the contrary, the number of Shares that may be issued or transferred pursuant to the rights granted under the Plan shall not exceed an aggregate of 10,000,000 Shares, subject to Article VIII.

3.2 Stock Distributed. Any Common Stock distributed pursuant to the Plan may consist, in whole or in part, of authorized and unissued Common Stock, treasury stock or Common Stock purchased on the open market.

### **ARTICLE IV. OFFERING PERIODS; OFFERING DOCUMENTS; PURCHASE DATES**

4.1 Offering Periods. The Administrator may from time to time grant or provide for the grant of rights to purchase Common Stock under the Plan to Eligible Employees during one or more periods (each, an “**Offering Period**”) selected by the Administrator. The terms and conditions applicable to each Offering Period shall be set forth in an “**Offering Document**” adopted by the Administrator, which Offering Document shall be in such form and shall contain such terms and conditions as the Administrator shall deem appropriate. The Administrator shall establish in each Offering Document one or more Purchase Periods during such Offering Period during which rights granted under the Plan shall be exercised and purchases of Shares carried out during such Offering Period in accordance with such Offering Document and the Plan. The provisions of separate Offering Periods under the Plan need not be identical.

4.2 Offering Documents. Each Offering Document with respect to an Offering Period shall specify (through incorporation of the provisions of this Plan by reference or otherwise):

- (a) the length of the Offering Period, which period shall not exceed 27 months;
- (b) the length of the Purchase Period(s) within the Offering Period;

(c) the maximum number of Shares that may be purchased by any Eligible Employee during such Offering Period, which, in the absence of a contrary designation by the Administrator, shall be 5,000 Shares;

(d) in connection with each Offering Period that contains more than one Purchase Period, the maximum aggregate number of Shares which may be purchased by any Eligible Employee during each Purchase Period, which, in the absence of a contrary designation by the Administrator, shall be 5,000 Shares; and

(e) such other provisions as the Administrator determines are appropriate, subject to the Plan.

## **ARTICLE V. ELIGIBILITY AND PARTICIPATION**

5.1 Eligibility. Any Eligible Employee who shall be employed by the Company or a Designated Subsidiary on a given Enrollment Date for an Offering Period shall be eligible to participate in the Plan during such Offering Period, subject to the requirements of this Article V and the limitations imposed by Section 423(b) of the Code.

### 5.2 Enrollment in Plan.

(a) Except as otherwise set forth in an Offering Document or determined by the Administrator, an Eligible Employee may become a Participant in the Plan for an Offering Period by delivering a subscription agreement to the Company by such time prior to the Enrollment Date for such Offering Period (or such other date specified in the Offering Document) designated by the Administrator and in such form as the Company provides.

(b) Each subscription agreement shall designate a whole percentage of such Eligible Employee's Compensation to be withheld by the Company or the Designated Subsidiary employing such Eligible Employee on each payday during the Offering Period as payroll deductions under the Plan. The designated percentage may not be less than 1% and may not be more than the maximum percentage specified by the Administrator in the applicable Offering Document (which percentage shall be 20% in the absence of any such designation). The payroll deductions made for each Participant shall be credited to an account for such Participant under the Plan and shall be deposited with the general funds of the Company.

(c) A Participant may decrease the percentage of Compensation designated in his or her subscription agreement, subject to the limits of this Section 5.2, or may suspend his or her payroll deductions, at any time during an Offering Period; provided, however, that the Administrator may limit the number of changes a Participant may make to his or her payroll deduction elections during each Offering Period in the applicable Offering Document (and in the absence of any specific designation by the Administrator, a Participant shall be allowed two decreases and one suspension (but no increases) to his or her payroll deduction elections during each Offering Period with respect to such Offering Period). Any such change or suspension of payroll deductions shall be effective with the first full payroll period following seven business days after the Company's receipt of the new subscription agreement (or such shorter or longer period as may be specified by the Administrator in the applicable Offering Document). In the event a Participant suspends his or her payroll deductions, such Participant's cumulative payroll deductions prior to the suspension shall remain in his or her account and shall be applied to the purchase of Shares on the next occurring Purchase Date and shall not be paid to such Participant unless he or she withdraws from participation in the Plan pursuant to Article VII.

(d) Except as otherwise set forth in Section 5.8 or in an Offering Document or determined by the Administrator, a Participant may participate in the Plan only by means of payroll deduction and may not make contributions by lump sum payment for any Offering Period.

5.3 Payroll Deductions. Except as otherwise provided in the applicable Offering Document or Section 5.8, payroll deductions for a Participant shall commence on the first payroll following the Enrollment Date and shall end on the last payroll in the Offering Period to which the Participant's authorization is applicable, unless sooner terminated by the Participant as provided in Article VII or suspended by the Participant or the Administrator as provided in Section 5.2 and Section 5.6, respectively.

5.4 Effect of Enrollment. A Participant's completion of a subscription agreement will enroll such Participant in the Plan for each subsequent Offering Period on the terms contained therein until the Participant either submits a new subscription agreement, withdraws from participation under the Plan as provided in Article VII or otherwise becomes ineligible to participate in the Plan.

5.5 Limitation on Purchase of Common Stock. An Eligible Employee may be granted rights under the Plan only if such rights, together with any other rights granted to such Eligible Employee under "employee stock purchase plans" of the Company, any Parent or any Subsidiary, as specified by Section 423(b)(8) of the Code, do not permit such employee's rights to purchase stock of the Company or any Parent or Subsidiary to accrue at a rate that exceeds \$25,000 of the fair market value of such stock (determined as of the first day of the Offering Period during which such rights are granted) for each calendar year in which such rights are outstanding at any time. This limitation shall be applied in accordance with Section 423(b)(8) of the Code.

5.6 Decrease or Suspension of Payroll Deductions. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 5.5 or the other limitations set forth in this Plan, a Participant's payroll deductions may be suspended by the Administrator at any time during an Offering Period. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares by reason of Section 423(b)(8) of the Code, Section 5.5 or the other limitations set forth in this Plan shall be paid to such Participant in one lump sum in cash as soon as reasonably practicable after the Purchase Date.

5.7 Foreign Employees. In order to facilitate participation in the Plan, the Administrator may provide for such special terms applicable to Participants who are citizens or residents of a foreign jurisdiction, or who are employed by a Designated Subsidiary outside of the United States, as the Administrator may consider necessary or appropriate to accommodate differences in local law, tax policy or custom. Such special terms may not be more favorable than the terms of rights granted under the Plan to Eligible Employees who are residents of the United States. Moreover, the Administrator may approve such supplements to, or amendments, restatements or alternative versions of, this Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of this Plan as in effect for any other purpose. No such special terms, supplements, amendments or restatements shall include any provisions that are inconsistent with the terms of this Plan as then in effect unless this Plan could have been amended to eliminate such inconsistency without further approval by the stockholders of the Company.

5.8 Leave of Absence. During leaves of absence approved by the Company meeting the requirements of Treasury Regulation Section 1.421-1(h)(2) under the Code, a Participant may continue participation in the Plan by making cash payments to the Company on his or her normal payday equal to his or her authorized payroll deduction.



**ARTICLE VI.  
GRANT AND EXERCISE OF RIGHTS**

6.1 Grant of Rights. On the Enrollment Date of each Offering Period, each Eligible Employee participating in such Offering Period shall be granted a right to purchase the maximum number of Shares specified under Section 4.2, subject to the limits in Section 5.5, and shall have the right to buy, on each Purchase Date during such Offering Period (at the applicable Purchase Price), such number of whole Shares as is determined by dividing (a) such Participant's payroll deductions accumulated prior to such Purchase Date and retained in the Participant's account as of the Purchase Date, by (b) the applicable Purchase Price (rounded down to the nearest Share). The right shall expire on the earlier of: (x) the last Purchase Date of the Offering Period, (y) last day of the Offering Period and (z) the date on which the Participant withdraws in accordance with Section 7.1 or Section 7.3.

6.2 Exercise of Rights. On each Purchase Date, each Participant's accumulated payroll deductions and any other additional payments specifically provided for in the applicable Offering Document will be applied to the purchase of whole Shares, up to the maximum number of Shares permitted pursuant to the terms of the Plan and the applicable Offering Document, at the Purchase Price. No fractional Shares shall be issued upon the exercise of rights granted under the Plan, unless the Offering Document specifically provides otherwise. Any cash in lieu of fractional Shares remaining after the purchase of whole Shares upon exercise of a purchase right will be carried forward and applied toward the purchase of whole Shares for the following Offering Period, unless the Administrator provides in the applicable Offering Document that such amounts shall be credited to a Participant's account and returned to the Participant in one lump sum payment in a subsequent payroll check as soon as practicable after the exercise date. Shares issued pursuant to the Plan may be evidenced in such manner as the Administrator may determine and may be issued in certificated form or issued pursuant to book-entry procedures.

6.3 Pro Rata Allocation of Shares. If the Administrator determines that, on a given Purchase Date, the number of Shares with respect to which rights are to be exercised may exceed (a) the number of Shares that were available for issuance under the Plan on the Enrollment Date of the applicable Offering Period, or (b) the number of Shares available for issuance under the Plan on such Purchase Date, the Administrator may in its sole discretion provide that the Company shall make a pro rata allocation of the Shares available for purchase on such Enrollment Date or Purchase Date, as applicable, in as uniform a manner as shall be practicable and as it shall determine in its sole discretion to be equitable among all Participants for whom rights to purchase Common Stock are to be exercised pursuant to this Article VI on such Purchase Date, and shall either (i) continue all Offering Periods then in effect, or (ii) terminate any or all Offering Periods then in effect pursuant to Article IX. The Company may make pro rata allocation of the Shares available on the Enrollment Date of any applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional Shares for issuance under the Plan by the Company's stockholders subsequent to such Enrollment Date. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares shall be paid to such Participant in one lump sum in cash as soon as reasonably practicable after the Purchase Date.

6.4 Withholding. At the time a Participant's rights under the Plan are exercised, in whole or in part, or at the time some or all of the Common Stock issued under the Plan is disposed of, the Participant must make adequate provision for the Company's federal, state, or other tax withholding obligations, if any, that arise upon the exercise of the right or the disposition of the Common Stock. At any time, the Company may, but shall not be obligated to, withhold from the Participant's Compensation the amount necessary for the Company to meet applicable withholding obligations, including any withholding required to make available to the Company any tax deductions or benefits attributable to sale or early disposition of Common Stock by the Participant.

6.5 Conditions to Issuance of Common Stock. The Company shall not be required to issue or deliver any certificate or certificates for, or make any book entries evidencing, Shares purchased upon the exercise of rights under the Plan prior to fulfillment of all of the following conditions:

- (a) The admission of such Shares to listing on all stock exchanges, if any, on which the Common Stock is then listed;
- (b) The completion of any registration or other qualification of such Shares under any state or federal law or under the rulings or regulations of the Securities and Exchange Commission or any other governmental regulatory body, that the Administrator shall, in its absolute discretion, deem necessary or advisable;
- (c) The obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable;
- (d) The payment to the Company of all amounts that it is required to withhold under federal, state or local law upon exercise of the rights, if any; and
- (e) The lapse of such reasonable period of time following the exercise of the rights as the Administrator may from time to time establish for reasons of administrative convenience.

#### **ARTICLE VII. WITHDRAWAL; CESSATION OF ELIGIBILITY**

7.1 Withdrawal. A Participant may withdraw all but not less than all of the payroll deductions credited to his or her account and not yet used to exercise his or her rights under the Plan at any time by giving written notice to the Company in a form acceptable to the Company no later than two weeks prior to the end of the Offering Period (or such shorter or longer period specified by the Administrator in the Offering Document). All of the Participant's payroll deductions credited to his or her account during an Offering Period shall be paid to such Participant as soon as reasonably practicable after receipt of notice of withdrawal and such Participant's rights for the Offering Period shall be automatically terminated, and no further payroll deductions for the purchase of Shares shall be made for such Offering Period. If a Participant withdraws from an Offering Period, payroll deductions shall not resume at the beginning of the next Offering Period unless the Participant is an Eligible Employee and timely delivers to the Company a new subscription agreement.

7.2 Future Participation. A Participant's withdrawal from an Offering Period shall not have any effect upon his or her eligibility to participate in any similar plan that may hereafter be adopted by the Company or a Designated Subsidiary or in subsequent Offering Periods that commence after the termination of the Offering Period from which the Participant withdraws.

7.3 Cessation of Eligibility. Upon a Participant's ceasing to be an Eligible Employee for any reason, he or she shall be deemed to have elected to withdraw from the Plan pursuant to this Article VII and the payroll deductions credited to such Participant's account during the Offering Period shall be paid to such Participant or, in the case of his or her death, to the person or persons entitled thereto under Section 12.4, as soon as reasonably practicable, and such Participant's rights for the Offering Period shall be automatically terminated.

**ARTICLE VIII.**  
**ADJUSTMENTS UPON CHANGES IN STOCK**

8.1 Changes in Capitalization. Subject to Section 8.3, in the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), Change in Control, reorganization, merger, amalgamation, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any outstanding purchase rights under the Plan, the Administrator shall make equitable adjustments, if any, to reflect such change with respect to (a) the aggregate number and type of Shares (or other securities or property) that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 and the limitations established in each Offering Document pursuant to Section 4.2 on the maximum number of Shares that may be purchased); (b) the class(es) and number of Shares and price per Share subject to outstanding rights; and (c) the Purchase Price with respect to any outstanding rights.

8.2 Other Adjustments. Subject to Section 8.3, in the event of any transaction or event described in Section 8.1 or any unusual or nonrecurring transactions or events affecting the Company, any affiliate of the Company, or the financial statements of the Company or any affiliate (including without limitation any Change in Control), or of changes in Applicable Law or accounting principles, the Administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent the dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any right under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(a) To provide for either (i) termination of any outstanding right in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such right had such right been currently exercisable or (ii) the replacement of such outstanding right with other rights or property selected by the Administrator in its sole discretion;

(b) To provide that the outstanding rights under the Plan shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar rights covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(c) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding rights under the Plan and/or in the terms and conditions of outstanding rights and rights that may be granted in the future;

(d) To provide that Participants' accumulated payroll deductions may be used to purchase Common Stock prior to the next occurring Purchase Date on such date as the Administrator determines in its sole discretion and the Participants' rights under the ongoing Offering Period(s) shall be terminated; and

(e) To provide that all outstanding rights shall terminate without being exercised.

8.3 No Adjustment Under Certain Circumstances. No adjustment or action described in this Article VIII or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to fail to satisfy the requirements of Section 423 of the Code.

8.4 No Other Rights. Except as expressly provided in the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of Shares subject to outstanding rights under the Plan or the Purchase Price with respect to any outstanding rights.

## **ARTICLE IX. AMENDMENT, MODIFICATION AND TERMINATION**

9.1 Amendment, Modification and Termination. The Administrator may amend, suspend or terminate the Plan at any time and from time to time; provided, however, that approval of the Company's stockholders shall be required to amend the Plan to: (a) increase the aggregate number, or change the type, of shares that may be sold pursuant to rights under the Plan under Section 3.1 (other than an adjustment as provided by Article VIII); (b) change the corporations or classes of corporations whose employees may be granted rights under the Plan; or (c) change the Plan in any manner that would cause the Plan to no longer be an "employee stock purchase plan" within the meaning of Section 423(b) of the Code.

9.2 Certain Changes to Plan. Without stockholder consent and without regard to whether any Participant rights may be considered to have been adversely affected, to the extent permitted by Section 423 of the Code, the Administrator shall be entitled to change or terminate the Offering Periods, limit the frequency and/or number of changes in the amount withheld from Compensation during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of payroll withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Common Stock for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Administrator determines in its sole discretion to be advisable that are consistent with the Plan.

9.3 Actions In the Event of Unfavorable Financial Accounting Consequences. In the event the Administrator determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Administrator may, in its discretion and, to the extent necessary or desirable, modify or amend the Plan to reduce or eliminate such accounting consequence including, but not limited to:

- (a) altering the Purchase Price for any Offering Period including an Offering Period underway at the time of the change in Purchase Price;
- (b) shortening any Offering Period so that the Offering Period ends on a new Purchase Date, including an Offering Period underway at the time of the Administrator action; and
- (c) allocating Shares.

Such modifications or amendments shall not require stockholder approval or the consent of any Participant.

9.4 Payments Upon Termination of Plan. Upon termination of the Plan, the balance in each Participant's Plan account shall be refunded as soon as practicable after such termination, without any interest thereon.

**ARTICLE X.  
TERM OF PLAN**

The Plan shall be effective on the Effective Date. The effectiveness of the Plan shall be subject to approval of the Plan by the stockholders of the Company within 12 months following the date the Plan is first approved by the Board. No right may be granted under the Plan prior to such stockholder approval. No rights may be granted under the Plan during any period of suspension of the Plan or after termination of the Plan.

**ARTICLE XI.  
ADMINISTRATION**

11.1 Administrator. Unless otherwise determined by the Board, the Administrator of the Plan shall be the Compensation Committee of the Board (or another committee or a subcommittee of the Board to which the Board delegates administration of the Plan) (such committee, the "**Committee**"). The Board may at any time vest in the Board any authority or duties for administration of the Plan.

11.2 Action by the Administrator. Unless otherwise established by the Board or in any charter of the Administrator, a majority of the Administrator shall constitute a quorum. The acts of a majority of the members present at any meeting at which a quorum is present and, subject to Applicable Law and the Bylaws of the Company, acts approved in writing by a majority of the Administrator in lieu of a meeting, shall be deemed the acts of the Administrator. Each member of the Administrator is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Designated Subsidiary, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

11.3 Authority of Administrator. The Administrator shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

- (a) To determine when and how rights to purchase Common Stock shall be granted and the provisions of each offering of such rights (which need not be identical).
- (b) To designate from time to time which Subsidiaries of the Company shall be Designated Subsidiaries, which designation may be made without the approval of the stockholders of the Company.
- (c) To construe and interpret the Plan and rights granted under it, and to establish, amend and revoke rules and regulations for its administration. The Administrator, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.
- (d) To amend, suspend or terminate the Plan as provided in Article IX.

(e) Generally, to exercise such powers and to perform such acts as the Administrator deems necessary or expedient to promote the best interests of the Company and its Subsidiaries and to carry out the intent that the Plan be treated as an “employee stock purchase plan” within the meaning of Section 423 of the Code.

11.4 Decisions Binding. The Administrator’s interpretation of the Plan, any rights granted pursuant to the Plan, any subscription agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding, and conclusive on all parties.

## **ARTICLE XII. MISCELLANEOUS**

12.1 Restriction upon Assignment. A right granted under the Plan shall not be transferable other than by will or the applicable laws of descent and distribution, and is exercisable during the Participant’s lifetime only by the Participant. Except as provided in Section 12.4 hereof, a right under the Plan may not be exercised to any extent except by the Participant. The Company shall not recognize and shall be under no duty to recognize any assignment or alienation of the Participant’s interest in the Plan, the Participant’s rights under the Plan or any rights thereunder.

12.2 Rights as a Stockholder. With respect to Shares subject to a right granted under the Plan, a Participant shall not be deemed to be a stockholder of the Company, and the Participant shall not have any of the rights or privileges of a stockholder, until such Shares have been issued to the Participant or his or her nominee following exercise of the Participant’s rights under the Plan. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash securities, or other property) or distribution or other rights for which the record date occurs prior to the date of such issuance, except as otherwise expressly provided herein or as determined by the Administrator.

12.3 Interest. No interest shall accrue on the payroll deductions or contributions of a Participant under the Plan.

12.4 Designation of Beneficiary.

(a) A Participant may, in the manner determined by the Administrator, file a written designation of a beneficiary who is to receive any Shares and/or cash, if any, from the Participant’s account under the Plan in the event of such Participant’s death subsequent to a Purchase Date on which the Participant’s rights are exercised but prior to delivery to such Participant of such Shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant’s account under the Plan in the event of such Participant’s death prior to exercise of the Participant’s rights under the Plan. If the Participant is married and resides in a community property state, a designation of a person other than the Participant’s spouse as his or her beneficiary shall not be effective without the prior written consent of the Participant’s spouse.

(b) Such designation of beneficiary may be changed by the Participant at any time by written notice to the Company. In the event of the death of a Participant and in the absence of a beneficiary validly designated under the Plan who is living at the time of such Participant’s death, the Company shall deliver such Shares and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of the Company), the Company, in its discretion, may deliver such Shares and/or cash to the spouse or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

12.5 Notices. All notices or other communications by a Participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

12.6 Equal Rights and Privileges. Subject to Section 5.7, all Eligible Employees will have equal rights and privileges under this Plan so that this Plan qualifies as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Subject to Section 5.7, any provision of this Plan that is inconsistent with Section 423 of the Code will, without further act or amendment by the Company, the Board or the Administrator, be reformed to comply with the equal rights and privileges requirement of Section 423 of the Code.

12.7 Use of Funds. All payroll deductions received or held by the Company under the Plan may be used by the Company for any corporate purpose, and the Company shall not be obligated to segregate such payroll deductions.

12.8 Reports. Statements of account shall be given to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of Shares purchased and the remaining cash balance, if any.

12.9 No Employment Rights. Nothing in the Plan shall be construed to give any person (including any Eligible Employee or Participant) the right to remain in the employ of the Company or any Parent or Subsidiary or affect the right of the Company or any Parent or Subsidiary to terminate the employment of any person (including any Eligible Employee or Participant) at any time, with or without cause.

12.10 Notice of Disposition of Shares. Each Participant shall give prompt notice to the Company of any disposition or other transfer of any Shares purchased upon exercise of a right under the Plan if such disposition or transfer is made: (a) within two years from the Enrollment Date of the Offering Period in which the Shares were purchased or (b) within one year after the Purchase Date on which such Shares were purchased. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

12.11 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

12.12 Electronic Forms. To the extent permitted by Applicable Law and in the discretion of the Administrator, an Eligible Employee may submit any form or notice as set forth herein by means of an electronic form approved by the Administrator. Before the commencement of an Offering Period, the Administrator shall prescribe the time limits within which any such electronic form shall be submitted to the Administrator with respect to such Offering Period in order to be a valid election.

\* \* \* \* \*

## HARMONY BIOSCIENCES, LLC

**AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT**

THIS AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT (the "Agreement"), dated as of August 11, 2020, is made by and between Harmony Biosciences, LLC a Delaware limited liability company (the "Company"), and John Jacobs (the "Executive").

**W I T N E S S E T H:**

**WHEREAS**, the Executive currently serves as the President and Chief Executive Officer of the Company pursuant to that certain Executive Employment Agreement, dated as of September 6, 2017 (the "Prior Employment Agreement"); and

**WHEREAS**, the Company and the Executive mutually desire to continue the employ of the Executive, under the terms and conditions set forth herein and to replace and supersede the Prior Employment Agreement, in any case, effective as of the closing of the Commencement Date (as defined below).

**NOW, THEREFORE**, for and in consideration of the mutual promises, covenants and obligations contained herein, the Company and the Executive agree as follows:

**ARTICLE I**  
**EMPLOYMENT AND DUTIES**

**Section 1.01 Employment and Term**. The term of the Executive's employment under this Agreement (the "Term") shall commence upon the date of the consummation of an initial public offering of Parent's (as defined below) common stock (the "Parent IPO") and the date that the Parent IPO is consummated, the "Commencement Date") and shall continue until the occurrence of a termination event as described in this Agreement.

**Section 1.02 Position and Duties**. The Executive shall, during the Term, serve as President and Chief Executive Officer of the Company, and shall report directly to the Board (as defined below). The Executive shall have the duties and responsibilities customarily associated with such position and will perform such other duties or serve in such other capacities as reasonably directed by the Board from time to time consistent with his position(s) hereunder. The Executive's primary work location shall be at the Company's principal offices located in Philadelphia, PA.

**Section 1.03 Scope**. The Executive will devote substantially all of his business time, attention, skills and efforts to the performance of his duties. The Executive acknowledges that his duties and responsibilities require the Executive's full-time business efforts, and agrees to not engage in any other business activity or interests which materially interfere or conflict with the performance of the Executive's duties.



**ARTICLE II**  
**COMPENSATION AND BENEFITS**

**Section 2.01 Base Salary.** During the Term, the Company will pay the Executive a base salary (the "Base Salary") of \$473,068 per year, pro-rated for partial years of service, in accordance with the Company's standard payroll practices and procedures. The Base Salary will be reviewed annually by the Board of Directors or, if applicable, its Compensation Committee (as the case may be, the "Board") of Harmony Biosciences Holdings, Inc., a Delaware corporation and the sole member of the Company (the "Parent"), but may only be decreased during the Term in connection with a one-time across-the-board annual base salary reduction of the other members of the Company's senior management team of no more than 10% (in which case such increased or decreased amount shall be the "Base Salary").

**Section 2.02 Bonus.** During the Term, the Executive shall be eligible to receive annual discretionary bonuses in the form of short-term cash incentive compensation (the "Short Term Incentive"), in an amount (if any) to be determined by the Board or its Compensation Committee, in its sole, nonreviewable discretion, based upon the Executive's performance meeting Board established individual goals and objectives to meet the growth strategy of the Company, as well as the Company's overall performance. Without limiting the generality of the Board's discretion, the Executive's target Short Term Incentive per annum shall be 50% of the Executive's Base Salary (the "Target Bonus"), and the Executive's maximum Short Term Incentive amount per annum will be equal to 75% of the Executive's Base Salary. Any Short Term Incentive shall be deemed earned on the date it is paid, provided, however, that, except as otherwise provided in Article III of this Agreement, the Executive must be employed by the Company on the date the Short-Term Incentives are paid in order for the Executive to be entitled to receive any payment of Short Term Incentive. The payment of the Short Term Incentive (if any) will be determined in the Company's sole discretion and paid to the Executive (to the extent payable) on the date on which annual bonuses are paid generally to the Company's senior executives; however, in no event will any Short Term Incentive be paid later than March 15th following the year to which it pertains.

**Section 2.03 Parent Equity.** Pursuant to the Prior Employment Agreement, and subject to the Executive's stock option agreement approved by the Board (the "Stock Option Agreement"), the Executive was granted a nonqualified stock option (the "Stock Option") under that certain Equity Incentive Plan of the Parent (the "Plan") to purchase shares of common stock of the Parent at a per share exercise price equal to or greater than the fair market value per share of common stock of the Parent as of the date of grant, as determined by the Board (in accordance with Section 409A ("Section 409A") of the Internal Revenue Code of 1986, as amended (the "Code")). The Stock Option shall continue to time vest as to 20% of the shares of common stock subject to the Stock Option on each of the first five anniversaries of the grant date, provided that the Executive remains employed by the Company through each such anniversary date, shall become fully vested as provided for in the Plan upon the consummation of a Change in Control (as defined in the Plan) (provided that the Executive remains employed by the Company through the date of consummation of such Change in Control) and shall otherwise be subject to the terms of the Stock Option Agreement described above and the Plan (which Plan shall have a ten year term, unless the Board terminates the Plan early as permitted in the Plan, in which case the Stock Option, if still outstanding as of such termination, shall expressly survive such termination and remain outstanding in accordance with the terms of the Plan, the Stock Option Agreement and this Agreement thereafter), including, but not limited to, the termination, forfeiture, repurchase and change of control provisions contained therein.

**Section 2.04 Expenses.** Subject to the Company's standard policies and procedures for expense reimbursement as applied to its executive employees generally, the Company shall reimburse the Executive for, or pay on behalf of the Executive, reasonable out-of-pocket business expenses incurred by the Executive on behalf of the Company, including airfare and other approved travel expenses as provided for in the Company's standard travel policies and procedures.

**Section 2.05 Reserved.**

**Section 2.06 Other Company Benefits.** During the Term, the Executive shall be eligible to participate in all employee benefit plans and programs maintained by the Company that are available to Company management personnel of comparable responsibilities, subject to the terms and conditions of such plans and programs which may be amended from time to time by the Company.

**Section 2.07 Vacation.** During the Term, the Executive shall be entitled to accrue up to twenty (20) paid vacation days in each full calendar year, which shall be accrued ratably at a rate of 1.66 days per full calendar month. In other respects, the Company's vacation policies and practices shall apply to vacations. The Executive shall also be entitled to all paid holidays given by the Company generally to its executives. Unless otherwise required by law or express, written Company policy, any accrued, unused vacation days remaining at the end of a given calendar year during the Executive's employment or remaining on the Termination Date (as defined, below) shall be forfeited and the Executive shall not be paid therefore. Notwithstanding the foregoing sentence, the Company may, as determined in its sole discretion, permit the Executive to carry over some, all or none of any accrued unused vacation days from one calendar year into the next calendar year during the Executive's employment with the Company.

### **ARTICLE III** **TERMINATION**

**Section 3.01 Termination of Employment.** During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) **Death.** The Executive's employment hereunder shall terminate upon his death.

(b) **Disability.** The Company may terminate the Executive's employment if he is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the

Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3.01(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 et seq. and the Americans with Disabilities Act, 42 U.S.C. § 12101 et seq.

(c) Termination by the Company for Cause. The Company may terminate the Executive's employment hereunder at any time for Cause. "Cause" shall exist with respect to the Executive for purposes of this Agreement if the Executive has:

- (i) willfully failed to perform his material duties (other than any such failure resulting from the Executive's incapacity due to physical or mental illness);
- (ii) willfully failed to comply with any valid and legal directive of the Board;
- (iii) engaged in dishonesty, illegal conduct or misconduct, which is, in each case, materially injurious to the Company or any of its affiliates or any member of the Company Group (as defined below);
- (iv) embezzled, misappropriated funds or other assets or committed fraud, whether or not related to the Executive's employment with the Company;
- (v) been convicted of or pleaded guilty or *nolo contendere* in respect of any crime that constitutes a felony (or state law equivalent) or any other crime that constitutes a misdemeanor involving moral turpitude, whether or not related to the Executive's employment with the Company;
- (vi) willfully violated a material policy of the Company; and/or
- (vii) materially breached any material obligation under this Agreement.

Notwithstanding anything to the contrary contained herein, if the Executive is terminated by the Company for Cause, but an arbitrator or court makes a determination, which determination is not subject to further appeal or after any right to appeal has expired, that adequate grounds for Cause did not exist, then such termination shall be deemed a termination without Cause for all purposes hereunder.

(d) Termination Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. A termination without Cause is any termination that does not: (i) constitute a termination by the Company for Cause under Section 3.01(c); (ii) result from the death or disability of the Executive under Sections 3.01(a) or (b); or (iii) result from the Executive's resignation for any reason (including, without limitation, Executive's resignation with or without Good Reason and any Accelerated Resignation (each, as defined below)).

(e) Termination by the Executive. The Executive may terminate the Executive's employment hereunder at any time for any reason, including but not limited to with or without Good Reason, subject to applicable notice periods and requirements as set forth herein. "Good Reason" means, for purposes of this Agreement, the occurrence of any one or more of the following events without the Executive's prior written consent: (a) the assignment to the Executive of any duties materially and adversely inconsistent with the Executive's position, duties and responsibilities (including reporting relationships or status with the Company), or a material reduction in the scope of the Executive's duties or responsibilities (including reporting relationships); (b) a material reduction in the Executive's Base Salary and/or Target Bonus, except for across-the-board annual base salary reductions or target bonus reductions for the Company's senior executives; (c) the Company's (i) relocation of its principal executive office in Philadelphia, PA to a location more than fifty miles (or such longer distance that is the minimum permissible distance under the circumstances for purposes of the involuntary separation from service standards under the Treasury Regulations or other guidance under Section 409A) from such principal executive office and (ii) requiring the Executive to relocate his principal work location to such new principal executive office (except for required travel on business for the Company Group), but only if such relocation results in a material increase to Executive's normal daily commute; (d) in the case of a Change in Control, the failure of the Company to cause a successor entity to assume and agree to perform this Agreement; or (e) any material breach by the Company of any material provision of this Agreement. Notwithstanding the foregoing, the Executive's employment will not be deemed to have resigned for Good Reason unless (i) the Executive provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by the Executive to constitute Good Reason within 30 days after the date of the occurrence of any event that the Executive knows or should reasonably have known to constitute Good Reason, (ii) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (iii) the effective date of the Executive's termination for Good Reason occurs no later than 30 days after the expiration of the Company's cure period.

(f) Notice of Termination. Except for termination as specified in Section 3.01(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Termination Date. "Termination Date" shall mean: (i) if the Executive's employment is terminated on account of his death under Section 3.01(a), the date of his death; (ii) if the Executive's employment is terminated on account of disability under Section 3.01(b) or by the Company for Cause under Section 3.01(c), the date on which a Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company without Cause under Section 3.01(d), the date on which a Notice of Termination is given; (iv) if the Executive's employment is terminated by the Executive under Section 3.01(e) without Good Reason, 30 days after the date on which a Notice of Termination is given; and (v) if the Executive's employment is terminated by the Executive under Section 3.01(e) with Good Reason, the effective date of such termination as determined under Section 3.01(e) with respect to a termination with Good Reason. Notwithstanding the foregoing, in the event that the Executive resigns for any reason (other than a resignation with Good Reason) and gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Termination Date to any earlier effective date (an "Accelerated Resignation") and such Accelerated Resignation shall not result in or be treated as a termination by the Company as of such earlier effective date for purposes of this Agreement.

**Section 3.02 Accrued Obligations.** In the event of any termination of the Executive's employment pursuant to Section 3.01 above, the Executive shall be entitled to receive his Accrued Obligations. As used in this Agreement, "Accrued Obligations" shall mean: (i) the Executive's earned but unpaid Base Salary through the Termination Date; (ii) any unpaid expense or other reimbursements due pursuant to Section 2.04 hereof; and (iii) vested employee benefits in accordance with the terms of the applicable employee benefit plans.

**Section 3.03 Compensation in the Event of Termination Without Cause or by the Executive With Good Reason not in Connection with a Change in Control.** During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3.01(d), or the Executive terminates his employment for Good Reason as provided in Section 3.01(e), then the Company shall pay the Executive his Accrued Obligations. In addition, subject to the Executive signing a general release and waiver of claims in favor of the Company, the other members of the Company Group and related persons and entities substantially in the form attached hereto as Exhibit A (the "General Release Agreement") and the General Release Agreement becoming irrevocable, all within 60 days after the Termination Date, and further subject to the Executive's compliance with Article IV, the Executive shall be entitled to receive:

(a) a cash amount equal to twelve (12) months of the annual Base Salary as in effect immediately prior to the Termination Date, paid in substantially equal installments as salary continuation for the twelve (12) months immediately following the Termination Date (such 12-month period, the "Severance Period") in accordance with the Company's normal payroll practices, provided that notwithstanding the foregoing, in no event shall any installment of such severance payments be paid prior to the sixtieth (60th) day following the Executive's Termination Date (the "Delayed Start Date") and any such installment that otherwise would have been paid between the Executive's Termination Date and the Delayed Start Date shall instead be paid in a lump sum on the Delayed Start Date (without interest);

(b) Subject to (x) the Executive's timely election of continuation coverage under Code Section 4980B ("COBRA") and (y) the Executive's continued copayment of premiums at the same level and cost to the Executive as if the Executive were an active employee of the Company, payment or reimbursement (as applicable) for the premiums for the Executive's health, medical and dental insurance coverage under the Company's group health plans, during the Severance Period (or until the date the Executive is eligible for health, medical and dental benefits by another employer, if earlier), to the same extent that the Company paid for such coverage immediately prior to the Executive's termination, in a manner intended to avoid any excise tax under Code Section 4980D, subject to the eligibility requirements and other terms and conditions of such insurance coverage; and

(c) Outplacement services consistent with those services customarily provided by the Company to its key employees for up to three (3) months immediately following the Termination Date or the date on which the Executive obtains other full-time employment, whichever occurs first.

**Section 3.04 Additional Compensation in the Event of Terminations in Connection with a Change in Control.**

(a) Subject to the terms of this Agreement, if during the twelve (12) month period following a Change in Control, the Executive's employment is terminated by the Company without Cause as provided in Section 3.01(d), or the Executive terminates his employment for Good Reason as provided in Section 3.01(e), then, in addition to the benefits provided for in Section 3.03, and subject to the Executive's timely execution and non-revocation of the General Release Agreement and the General Release Agreement becoming irrevocable, all within 60 days after the Termination Date, and further subject to the Executive's compliance with Article IV, below, the Executive shall be entitled to receive a pro rata lump sum cash payment equal to the Executive's Target Bonus for such calendar year, multiplied by a fraction the numerator of which is the number of days elapsed in the calendar year to and including the Termination Date and the denominator of which is 365.

(b) The following definitions shall apply:

(i) "Change in Control" means the occurrence of any of the following, as determined by the Board: (i) an acquisition by any Person of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 50% or more of the combined voting power of the Company's or Parent's (as applicable) equity; excluding, however, the following: (a) any acquisition by the Company or Parent (as applicable); (b) any acquisition by a lender to the Company or Parent (as applicable) pursuant to a debt restructuring thereof; (c) any acquisition by, or consummation of a Corporate Transaction with an affiliate of the Company or Parent (as applicable); or (d) a Non-Control Transaction; or (ii) a Corporate Transaction unless such Corporate Transaction is a Non-Control Transaction. Notwithstanding the foregoing, an event or occurrence described above shall not constitute a Change in Control, unless such event or occurrence also qualifies as a "change in control event" within the meaning of Code Section 409A. Further, notwithstanding the foregoing, an initial public offering or other sale of the Company's or Parent's (as applicable) equity by the Company or Parent (as applicable) pursuant to a registration statement filed with the United States Securities Exchange Commission under the Securities Exchange Act of 1934, as amended, shall not be deemed to constitute a Change in Control.

(ii) "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.

(iii) "Corporate Transaction" means the consummation of a reorganization, merger or consolidation involving the Company or Parent (as applicable) or the sale or other disposition of all or substantially all of the assets of the Company or Parent (as applicable), as determined by the Board.

(iv) “Non-Control Transaction” means a Corporate Transaction as a result of which the combined voting power of outstanding equity of the Company or Parent (as applicable) immediately prior to such Corporate Transaction will entitle the holders thereof immediately prior to such Corporate Transaction to exercise, directly or indirectly, more than 50% of the combined voting power (disregarding for this purpose the voting power related to any disproportionate and more than incidental increase in any holder’s voting power occurring in connection with or incident to the transaction) of all units or, if applicable, the shares of capital stock, entitled to vote generally in the election of the board of managers or directors of similar governing body of the entity resulting from such Corporate Transaction immediately after such Corporate Transaction (including, without limitation, a corporation which as the result of such transaction owns the Company or Parent (as applicable) or all or substantially all of the Company’s or Parent’s (as applicable) assets, either directly or through one or more subsidiaries).

**Section 3.05 Resignation from Positions.** Upon the termination of the Executive’s employment for any reason, the Executive shall immediately resign from each position held with the Company and its affiliates as of the Termination Date, including any position on the Board, if requested to do so by the Company.

**ARTICLE IV**  
**PROPRIETARY INFORMATION; RESTRICTIVE COVENANTS**

**Section 4.01 Definitions.** As used in this Article, the following definitions apply:

- (a) “Company Group” means the Company and its subsidiaries and Parent.
- (b) “Competing Business” means any business that competes with the business of the Company Group.

**Section 4.02 Confidential Information.**

(a) Obligation to Maintain Confidentiality. The Executive acknowledges that the information, observations and data obtained by him during the course of his performance under this Agreement concerning the business and affairs of the Company Group, including, but not limited to, information concerning acquisition opportunities in or reasonably related to the business of the Company Group (“Confidential Information”), of which the Executive becomes aware during the Term are the property of the Company Group. Therefore, the Executive agrees that he will not disclose to any unauthorized Person or use for his own account any Confidential Information without the Board’s written consent, unless and to the extent that the aforementioned matters (i) become generally known to and available for use by the public other than as a result of the Executive’s acts or omissions in breach of this Agreement, (ii) were known by the Executive prior to his commencement of service under the Prior Employment Agreement (other than Confidential Information disclosed to the Executive in confidence in connection with the Executive’s employment with the Company or another Company Group company), (iii) is required to be disclosed pursuant to any applicable law or court order or (iv) are in furtherance of the Executive’s duties under Section 1(a) hereof. The Executive agrees to deliver to the Company following his termination of employment, or at any other time the Company may request in writing, all memoranda, notes, plans, records, reports and other documents (and copies thereof) relating to the business of the Company Group (including, without limitation, all acquisition

prospects, lists and contact information) or containing Confidential Information which he may then possess or have under his control; provided that nothing herein shall preclude the Executive from retaining such documents and information as shall pertain to his rights hereunder or making such disclosure as shall be reasonably necessary to enforce any of the Executive's rights hereunder.

(b) Third Party Information. The Executive understands that the Company Group will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the part of the Company Group to maintain the confidentiality of such information and to use it only for certain limited purposes. During the Term and thereafter, and without in any way limiting the provisions of Section 2(a) above, the Executive will hold Third Party Information in strictest confidence and will not disclose to anyone (other than personnel, consultants, attorneys, accountants and other advisors of the Company Group who need to know such information in connection with their work for the Company Group) or use such Third Party Information, except to the extent that (i) such Third Party Information shall have become generally known to and available for use by the public other than as a result of the Executive's acts or omissions in breach of this Agreement, (ii) such Third Party Information is required to be disclosed pursuant to any applicable law or court order, (iii) the use of such Third Party Information is in furtherance of the Executive's duties under Section 1(a) hereof or (iv) the disclosure of such Third Party Information is expressly authorized by the Board in writing.

(c) Pursuant to the Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any Federal or state trade secret law for the disclosure of any Confidential Information that (i) is made (A) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (iii) if the Executive files a lawsuit for retaliation by his employer for reporting a suspected violation of law, the Executive may disclose trade secrets to his attorney and use the trade secret information in the court proceeding if the Executive: (x) files any document containing the trade secret under seal; and (y) does not disclose the trade secret, except pursuant to court order.

**Section 4.03 Noncompetition and Nonsolicitation**. The Executive acknowledges that in the course of his employment with the Company he will become familiar with trade secrets and other confidential information concerning the Company Group and that his services will be of special, unique and extraordinary value to the Company. Therefore, the Executive agrees that:

(a) Noncompetition. During the Term and for a period of one year thereafter, the Executive shall not, anywhere in the world, directly or indirectly own, manage, control, participate in, consult with, render services for, or in any manner engage in any business that is a Competing Business as of the relevant date of determination. Nothing herein shall prohibit the Executive from being a passive owner of not more than 5% of the outstanding stock of any class of any entity that is publicly traded, so long as the Executive has no active participation in the business of such entity. For purposes of this Agreement, the "relevant date of determination" shall mean (x) the date upon which the Executive commences to engage in such activity with respect to any activity commenced during the Term, or (y) the Termination Date with respect to any activity Executive commences to engage in after the Termination Date.



(b) **Nonsolicitation.** During the Term and for a period of one year thereafter, the Executive shall not, other than in the good faith performance of his duties for the Company hereunder, directly or indirectly through another entity induce or attempt to induce any employee of the Company Group to leave the employ of any member of the Company Group.

**Section 4.04 Enforcement.** If, at the time of enforcement of Section 4.03, a court holds that the restrictions stated therein or herein are unreasonable under circumstances then existing, the parties hereto agree that the maximum duration, scope or geographical area reasonable under such circumstances shall be substituted for the stated period, scope or area and that the court shall be allowed to revise the restrictions contained herein to cover the maximum duration, scope and area permitted by law. Because the Executive's services are unique and because the Executive has access to Confidential Information, the parties hereto agree that money damages would be an inadequate remedy for any breach of this Agreement. Therefore, in the event a breach or threatened breach of this Agreement, the Company and its successors or permitted assigns may, in addition to other rights and remedies existing in their favor, apply to any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce, or prevent any violations of, the provisions hereof (without posting a bond or other security).

**Section 4.05 Additional Acknowledgments.** The Executive acknowledges that the provisions of this Article IV are in consideration of: (i) the Executive's continued employment with the Company, (ii) the equity interests described in Section 2.03, above, (iii) the severance payments described in Article III, and (iv) additional good and valuable consideration as set forth in this Agreement. In addition, the Executive agrees and acknowledges that the restrictions contained in this Article IV do not preclude the Executive from earning a livelihood, nor do they unreasonably impose limitations on the Executive's ability to earn a living. In addition, the Executive acknowledges (i) that the business of the Company Group is and will be international in scope and without geographical limitation, (ii) notwithstanding the state of incorporation/formation or principal office of the Company or any other member of the Company Group, it is expected that the Company Group has and will have business activities and valuable business relationships within its industry throughout the world, and (iii) as part of his responsibilities, the Executive will be traveling around the world in furtherance of the Company Group's business and relationships. The Executive agrees and acknowledges that the potential harm to the Company Group of the non-enforcement of this Article IV outweighs any potential harm to the Executive of their enforcement by injunction or otherwise. The Executive acknowledges that he has carefully read this Agreement and has given careful consideration to the restraints imposed upon the Executive by this Agreement, and is in full accord as to their necessity for the reasonable and proper protection of Confidential Information. The Executive expressly acknowledges and agrees that each and every restraint imposed by this Agreement is reasonable with respect to subject matter, time period and geographical area.

## **ARTICLE V MISCELLANEOUS**

**Section 5.01 Withholding.** The Company shall withhold all applicable federal, state and local taxes, social security and workers' compensation contributions and other amounts as may be required by law with respect to compensation payable to the Executive.

**Section 5.02 Section 409A.**

(a) Notwithstanding anything herein to the contrary, this Agreement is intended to be interpreted and applied so that the payment of the benefits set forth herein either shall either be exempt from the requirements of Section 409A or shall comply with the requirements of such provision.

(b) Notwithstanding any provision of this Agreement to the contrary, if the Executive is a “specified employee” within the meaning of Section 409A, any payments or arrangements due upon a termination of the Executive’s employment under any arrangement that constitutes a “nonqualified deferral of compensation” within the meaning of Section 409A and which do not otherwise qualify under the exemptions under Treas. Regs. Section 1.409A-1 (including without limitation, the short-term deferral exemption or the permitted payments under Treas. Regs. Section 1.409A-1(b)(9)(iii)(A)), shall be delayed and paid or provided, without interest, on the earlier of (i) the date which is six months after the Executive’s “separation from service” (as such term is defined in Section 409A and the regulations and other published guidance thereunder) for any reason other than death, and (ii) the date of the Executive’s death.

(c) After any Termination Date, the Executive shall have no duties or responsibilities that are inconsistent with having a “separation from service” within the meaning of Section 409A and, notwithstanding anything in the Agreement to the contrary, distributions upon termination of employment of nonqualified deferred compensation may only be made upon a “separation from service” as determined under Section 409A and such date shall be the Termination Date for purposes of this Agreement. Each payment under this Agreement or otherwise shall be treated as a separate payment for purposes of Section 409A. In no event may the Executive, directly or indirectly, designate the calendar year of any payment to be made under this Agreement which constitutes a “nonqualified deferral of compensation” within the meaning of Section 409A and to the extent an amount is payable within a time period, the time during which such amount is paid shall be in the discretion of the Company.

**Section 5.03 Merger Clause; Effectiveness.** As of the Commencement Date, this Agreement (together with exhibits attached hereto) contains the complete, full, final and exclusive understanding between the Executive and the Company as to its subject matter hereof and supersedes and replaces any prior term sheets, understandings or agreements between the Executive and the Company (and its affiliates), including, without limitation, the Prior Employment Agreement. The effectiveness of this Agreement is expressly made subject to and conditioned upon the consummation of the Parent IPO; in the event the Parent IPO is not consummated, this Agreement shall have no force or effect. As of the Commencement Date, the Prior Employment Agreement shall terminate and be of no further force or effect.

**Section 5.04 Assignment.**

(a) This Agreement is personal to the Executive. Neither the Company nor the Executive may make any assignment of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party. For purposes of this Section, consent on the part of the Company means the written, signed consent of the Board. Notwithstanding the foregoing, the Company may assign its rights under this Agreement without

any such further consent of the Executive to any successor in interest to the Company including in the event that the Company shall effect a reorganization, consolidate with or merge into any other corporation, limited liability company, partnership, organization or other entity, or transfer all or substantially all of its properties or assets to any other corporation, limited liability company, partnership, organization or other entity, in which event all references to the "Company" shall be deemed to mean the assignee or a designated affiliate of the assignee. The Executive hereby consents to such assignment as set forth in the immediately preceding sentence and further acknowledges and agrees that no further consent by the Executive is necessary to make such assignment. This Agreement shall inure to the benefit of and be binding upon the Company and the Executive, their respective successors, executors, administrators, heirs and permitted assigns.

(b) Notwithstanding the foregoing Section 5.04(a), this Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the Executive should die while any earned and unpaid amounts would otherwise still be payable to him hereunder if he had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to the Executive's devisee, legatee or other designee or, should there be no such designee, to the Executive's estate.

**Section 5.05 Dispute Resolution.** Except as provided in the last sentence of this Section, to the fullest extent permitted by law, the Company and the Executive agree to waive their rights to seek remedies in court, including any right to a jury trial. The Company and the Executive agree that any dispute between or among them or their subsidiaries, affiliates or related entities arising out of, relating to or in connection with this Agreement or the Executive's employment with the Company, will be resolved in accordance with a two-step dispute resolution procedure involving: (1) Step One: non-binding mediation, and (2) Step Two: binding arbitration under the Federal Arbitration Act, 9 U.S.C. section 1 et. seq., or state law, whichever is applicable. Any such mediation or arbitration hereunder shall be conducted in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the JAMS (f/k/a the Judicial Arbitration and Mediation Service) ("JAMS") pursuant to its then current JAMS Employment Arbitration Rules & Procedures (a copy of which is available through JAM's website, [www.jamsadr.org](http://www.jamsadr.org)) (the "JAMS Rules"). Notwithstanding anything to the contrary in the JAMS Rules, the mediation process (Step One) may be ended by either party to the dispute upon notice to the other party that it desires to terminate the mediation and proceed to the Step Two arbitration; provided, however, that neither party may so terminate the mediation process prior to the occurrence of at least one (1) mediation session with the mediator. No arbitration shall be initiated or take place with respect to a given dispute if the parties have successfully achieved a mutually agreed to resolution of the dispute as a result of the Step One mediation. The mediation session(s) and, if necessary, the arbitration hearing shall be held in Philadelphia, Pennsylvania or any other location mutually agreed to by the parties hereto. The arbitration (if the dispute is not resolved by mediation) will be conducted by a single JAMS arbitrator, mutually selected by the parties, as provided for by the JAMS Rules. If required by law, the Company will be responsible for the JAMS charges, including the costs of the mediator and arbitrator, otherwise the parties will share such charges equally. The Company and the Executive agree that the arbitrator shall apply the substantive law of Delaware to all state law claims and federal law to any federal law claims, that discovery shall be conducted in accordance with the JAMS Rules or as otherwise permitted by law

as determined by the arbitrator. The arbitrator's award shall consist of a written statement as to the disposition of each claim and the relief, if any, awarded on each claim. The Company and the Executive understand that the right to appeal or to seek modification of any ruling or award by the arbitrator is limited under state and federal law. Any award rendered by the arbitrator will be final and binding, and judgment may be entered on it in any court of competent jurisdiction in Philadelphia, Pennsylvania at the time the award is rendered or as otherwise provided by law. Nothing contained herein shall restrict either party from seeking temporary injunctive relief in a court of law. The arbitrators are not empowered to award damages in excess of compensatory damages and each party irrevocably waives any damages in excess of compensatory damages. Judgment upon any arbitration award may be entered into any court having jurisdiction thereof and the parties consent to the jurisdiction of any court of competent jurisdiction located in the Commonwealth of Pennsylvania.

**Section 5.06 GOVERNING LAW.** THIS AGREEMENT SHALL BE DEEMED TO BE MADE IN THE STATE OF DELAWARE, INTERPRETATION, CONSTRUCTION AND PERFORMANCE OF THIS AGREEMENT IN ALL RESPECT SHALL BE GOVERNED BY THE LAWS OF THE STATE OF DELAWARE WITHOUT REGARD TO ITS PRINCIPLES OF CONFLICTS OF LAW.

**Section 5.07 Amendment; No Waiver.** No provision of this Agreement may be amended, modified, waived or discharged except by a written document signed by the Executive and duly authorized officer of the Company. The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered as a waiver of such party's rights or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. No failure or delay by any party in exercising any right or power hereunder will operate as a waiver thereof, nor will any single or partial exercise of any other right or power. No agreement or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by any party, which are not set forth expressly in this Agreement.

**Section 5.08 280G; Limitations on Payments.**

(a) Notwithstanding any other provision of this Agreement, in the event that any payment or benefit received or to be received by the Executive (including any payment or benefit received in connection with a termination of the Executive's employment, whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement) (all such payments and benefits, including the payments and benefits under Section 3.03 hereof, being hereinafter referred to as the "Total Payments") would be subject (in whole or part), to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then, after taking into account any reduction in the Total Payments provided by reason of Section 280G of the Code in such other plan, arrangement or agreement, the cash severance payments under this Agreement shall first be reduced, and the noncash severance payments hereunder shall thereafter be reduced, to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments) is greater than or equal to (ii) the net amount of such Total Payments without such

reduction (but after subtracting the net amount of federal, state and local income taxes on such Total Payments and the amount of Excise Tax to which the Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments). In all cases, if there are any reductions to the Total Payments under this paragraph, the reduction shall be performed in a manner which results in the greatest after-tax amount being retained by the Executive and in manner which comports with Section 409A.

(b) For purposes of determining whether and the extent to which the Total Payments will be subject to the Excise Tax, (i) no portion of the Total Payments the receipt or enjoyment of which the Executive shall have waived at such time and in such manner as not to constitute a "payment" within the meaning of Section 280G(b) of the Code shall be taken into account; (ii) no portion of the Total Payments shall be taken into account which, in the written opinion of an independent, nationally recognized accounting firm (the "Independent Advisors") selected by the Company (provided however that Independent Advisors may not without the Executive's written consent be the firm which serves as the auditor for the ultimate parent of the entity acquiring the Company) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) and, in calculating the Excise Tax, no portion of such Total Payments shall be taken into account which, in the opinion of Independent Advisors, constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation; and (iii) the value of any non-cash benefit or any deferred payment or benefit included in the Total Payments shall be determined by the Independent Advisors in accordance with the principles of Sections 280G(d)(3) and (4) of the Code.

**Section 5.09 Severability.** If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable law or public policy, all other conditions and provisions of this Agreement shall nonetheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated by this Agreement is not affected in any manner materially adverse to any party. Upon any such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

**Section 5.10 Survival.** The rights and obligations of the parties under the provisions of this Agreement that relate to post-termination obligations shall survive and remain binding and enforceable, notwithstanding the expiration of the term of this Agreement, the termination of the Executive's employment with the Company for any reason or any settlement of the financial rights and obligations arising from the Executive's employment hereunder, to the extent necessary to preserve the intended benefits of such provisions.

**Section 5.11 Notices.** All notices and other communications required or permitted by this Agreement will be made in writing and all such notices and communications will be deemed to have been duly given when delivered or (unless otherwise specified) emailed, mailed by United States certified or registered mail, return receipt requested, postage prepaid, addressed, if to the Company, at its principal office, and if to the Executive, at the Executive's last address on file with the Company. Either party may change such address from time to time by notice to the other.

**Section 5.12 Headings and References.** The headings of this Agreement are inserted for convenience only and neither constitute a part of this Agreement nor affect in any way the meaning or interpretation of this Agreement. When a reference in this Agreement is made to a Section, such reference shall be to a Section of this Agreement unless otherwise indicated.

**Section 5.13 Counterparts.** This Agreement may be executed in one or more counterparts (including via facsimile), each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

*[signature page follows]*

IN WITNESS WHEREOF, this Agreement has been executed by the parties as of the date first written above.

**HARMONY BIOSCIENCES, LLC**

By: /s/ Susan Drexler

Name: Susan Drexler

Title: Chief Financial Officer

**EXECUTIVE**

/s/ John Jacobs

Name: John Jacobs

[Signature Page to Amended and Restated Executive Employment Agreement]

EXHIBIT A

GENERAL RELEASE AND WAIVER

I, John Jacobs, in consideration of and subject to the performance by Harmony Biosciences, LLC, a Delaware limited liability company (the "Company"), of its obligations under the Amended and Restated Executive Employment Agreement, dated as of [DATE], 2020 (together with any amendments thereto, the "Agreement"), do hereby release and forever discharge as of the date hereof each of the Company, the other members of the Company Group, their respective affiliates and subsidiaries and all present and former members, managers, directors, officers, agents, representatives, employees, successors and assigns thereof (collectively, the "Released Parties") to the extent provided below. Capitalized terms used but not defined herein shall have the meanings given to them in the Agreement.

1. I understand that the payment of the payments pursuant to Section 3.03 [**and Section 3.04, if applicable**] of the Agreement (the "Severance Payments") represent, in part, consideration for signing this General Release and Waiver and is not salary, wages or benefits to which I was already entitled. I understand and agree that I will not receive the Severance Payments (a) unless I execute this General Release and Waiver and do not revoke this General Release and Waiver within the time period permitted hereafter, (b) if I breach this General Release and Waiver in any material respect or (c) if I breach any provision of Article IV of the Agreement. Such payment will not be considered compensation for purposes of any employee benefit plan, program, policy or arrangement maintained or hereafter established by the Company, the Company Group or any of their respective affiliates, subsidiaries or successors. Subject to the proviso set forth at the end of Section 2 below, I also acknowledge and represent that I have received all payments and benefits that I am entitled to receive (as of the date hereof) by virtue of any employment by the Company, the Company Group or their respective affiliates or subsidiaries.
2. Except as provided in Section 4 below and except for the provisions of the Agreement which expressly survive the termination of my employment with the Company, the Company Group or their respective affiliates or subsidiaries, I knowingly and voluntarily (for myself, my heirs, executors, attorneys, representatives, agents, administrators and assigns) fully and unconditionally release and forever discharge the Company, the Company Group and the other Released Parties from any and all claims, suits, controversies, actions, causes of action, cross-claims, counter-claims, demands, debts, compensatory damages, liquidated damages, punitive or exemplary damages, other damages, claims for costs and attorneys' fees, or liabilities of any nature whatsoever in law and in equity, both past and present (through the date this General Release and Waiver becomes effective and enforceable) and whether known or unknown, suspected, or claimed against the Company, the Company Group or any other Released Parties which I, my spouse, or any of my heirs, executors, attorneys, representatives, agents, administrators or assigns, may have, which arise out of or are connected with my employment with, or my separation or termination from, the Company, the Company Group or their respective affiliates or subsidiaries (including, but not limited to, any allegation, claim or violation, arising under: Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; the Age Discrimination in Employment Act of 1967, as amended (including the



Older Workers Benefit Protection Act); the Equal Pay Act of 1963, as amended; the Americans with Disabilities Act of 1990; the Family and Medical Leave Act of 1993; the Worker Adjustment Retraining and Notification Act; the Employee Retirement Income Security Act of 1974; Illinois and/or Pennsylvania Labor Laws or their state or local counterparts; or under any other federal, state or local civil or human rights law, or under any other local, state, or federal law, regulation or ordinance; or under any public policy, contract or tort, or under common law; or arising under any employment policies, practices or procedures of the Company, the Company Group or any of or any of their respective affiliates, subsidiaries or successors; or any claim for wrongful discharge, breach of contract, infliction of emotional distress, defamation; or any claim for costs, fees, or other expenses, including attorneys' fees incurred in these matters) (all of the foregoing collectively referred to herein as the "Claims"); provided, however, that this General Release and Waiver does not waive or release any rights or claims that I may have under or against the Released Parties arising out of any of the following (which shall be excluded from the definition of "Claims"): (a) any claims for the payment of earned but unpaid Base Salary through the Termination Date (b) any rights of indemnification or to advancement of expenses, whether pursuant to applicable law or contract, (c) any rights as an owner of equity in a Released Party, (d) any other vested or accrued amounts to which I am entitled under the express terms of any applicable executive or employee benefit plan, or (e) any claim that may not be waived as a matter of law, including, to the extent applicable, any right to receive an award for information provided to a government agency (except with respect to any discrimination charge filed with or investigation conducted by the Equal Employment Opportunity Commission (the "EEOC") and any similar state or local agency). For the purpose of implementing a full, knowing and complete release and discharge of the aforementioned Released Parties, I expressly acknowledge that this General Release and Waiver is intended to include in its effect, without limitation, all claims which I do not know or suspect to exist in my favor at the time of execution hereof, and that the Agreement contemplates the extinguishment of any such claim or claims.

3. I represent that I have made no assignment or transfer of any right, claim, demand, cause of action, or other matter covered by Section 2 above.
4. I agree that this General Release and Waiver does not waive or release any rights or claims that I may have under the Age Discrimination in Employment Act of 1967 which arise after the date I execute this General Release and Waiver. I acknowledge and agree that my separation from employment with the Company, the Company Group or their respective affiliates or subsidiaries in compliance with the terms of the Agreement shall not serve as the basis for any claim or action (including, without limitation, any claim under the Age Discrimination in Employment Act of 1967).
5. In signing this General Release and Waiver, I acknowledge and intend that it shall be effective as a bar to each and every one of the Claims hereinabove mentioned or implied. I expressly consent that this General Release and Waiver shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected Claims (notwithstanding any state statute that expressly limits the effectiveness of a general release of unknown, unsuspected or unanticipated Claims), if any, as well as those relating to any other Claims hereinabove mentioned or implied. I

acknowledge and agree that this waiver is an essential and material term of this General Release and Waiver and that without such waiver the Company would not have agreed to the terms of the Agreement. I further agree that in the event I should bring a Claim seeking damages against the Company, the Company Group or any other Released Party, or in the event I should seek to recover against Company, the Company Group or any other Released Party in any Claim brought by a governmental agency on my behalf, this General Release and Waiver shall serve as a complete defense to such Claims. I further waive any right to recovery in a proceeding instituted on my behalf by an administrative agency or other entity regarding my employment with, or separation from, the Company, the Company Group or their respective affiliates or subsidiaries. I further agree that I am not aware of any pending charge or complaint of the type described in Section 2 above as of the execution of this General Release and Waiver except for \_\_\_\_\_.

6. I represent that I am not aware of any Claim by me other than the claims that are released by this Agreement. I agree to expressly waive any rights I may have under any state statute that expressly limits the effectiveness of a general release of unknown, unsuspected or unanticipated Claims, as well as under any other statute or common law principles of similar effect.
7. I agree that neither this General Release and Waiver, nor the furnishing of the consideration for this General Release and Waiver, shall be deemed or construed at any time to be an admission by the Company, the Company Group, any other Released Party or myself of any improper or unlawful conduct.
8. I agree that I will forfeit the Severance Payments payable by the Company pursuant to the Agreement if I challenge the validity of this General Release and Waiver, provided, however, that the foregoing shall not release any right to challenge, under the Older Worker's Benefit Protection Act, the knowing and voluntary nature of the release of any age claims in this General Release and Waiver, in court or before the EEOC or any right to file an administrative charge with the EEOC or any other similar federal, state, or local agency (provided, that any right to recover monetary damages in any such proceeding shall be hereby released and waived).
9. I also agree that if I violate this General Release and Waiver by suing the Company, the Company Group or the other Released Parties in respect of a Claim, I will pay all reasonable costs and expenses of defending against the suit incurred by the Released Parties in the event that they are the prevailing party, including reasonable attorneys' fees, and return the Severance Payments received by me pursuant to the Agreement. I understand that, if I prevail in any action against the Company, the Company Group or any other Released Parties in respect of a Claim, Company will pay all of my reasonable costs and expenses that I incurred in conjunction with such action, including reasonable attorneys' fees.
10. I acknowledge and reaffirm my obligation to abide by the covenants set forth Article IV of the Agreement. I further agree that as of the date hereof, I have returned to the Company any and all property, tangible or intangible, relating to the Business, which I possessed or had control over at any time (including, but not limited to, company-provided credit cards,

building or office access cards, keys, computer equipment, manuals, files, documents, records, software, customer data base and other data) and that I shall not retain any copies, compilations, extracts, excerpts, summaries or other notes of any such manuals, files, documents, records, software, customer data base or other data, except to the extent that I am entitled to retain such materials under the provisions of Article IV of the Agreement.

11. Nothing in this General Release and Waiver prohibits me from reporting possible violations of federal law or regulation to any governmental agency or entity, or making other disclosures, that are protected under the whistleblower provisions of federal law or regulation (or similar state laws) or receipt of awards thereunder. I will not need the prior authorization of the Board or the Company Chairman to make any such reports or disclosures, and I will not be required to notify the Company that I have made such reports or disclosures, provided, that nothing shall waive any attorney client or similar privilege of the Company or the Company Group. I will not be held criminally or civilly liable under any federal or state trade secret law for any disclosure of a trade secret that is made (i) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document that is filed under seal in a lawsuit or other proceeding.
12. Notwithstanding anything in this General Release and Waiver to the contrary, this General Release and Waiver shall not relinquish, diminish, or in any way affect any rights or claims arising out of any breach by the Company or by any other Released Party of the Agreement after the date hereof.
13. I hereby waive any reinstatement or future employment with the Company, the Company Group or any of their respective affiliates or subsidiaries and agree never to apply for employment or otherwise seek to be hired, rehired, employed, reemployed, or reinstated by Company, the Company Group or any of their respective affiliates or subsidiaries without the prior written approval of the Company.
14. Whenever possible, each provision of this General Release and Waiver, shall be interpreted in, such manner as to be effective and valid under applicable law, but if any provision of this General Release and Waiver is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or any other jurisdiction, but this General Release and Waiver shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein. Upon a finding by a court of competent jurisdiction that any release or agreement in this General Release and Waiver is illegal, void or unenforceable, I agree, at the Company's option, to execute promptly a release and agreement that is legal and enforceable. My failure to comply with the obligations to promptly execute such release will constitute a material breach of this General Release and Waiver.

BY SIGNING THIS GENERAL RELEASE AND WAIVER, I REPRESENT AND AGREE THAT:

- (i) I HAVE READ IT CAREFULLY;
- (ii) I UNDERSTAND ALL OF ITS TERMS AND KNOW THAT I AM GIVING UP IMPORTANT RIGHTS, INCLUDING BUT NOT LIMITED TO, RIGHTS UNDER THE AGE DISCRIMINATION IN EMPLOYMENT ACT OF 1967, AS AMENDED, TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, AS AMENDED; THE EQUAL PAY ACT OF 1963, THE AMERICANS WITH DISABILITIES ACT OF 1990; AND THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974, AS AMENDED [**UPDATE AS OF SIGNING**];
- (iii) I VOLUNTARILY CONSENT TO EVERYTHING IN IT;
- (iv) I HAVE BEEN ADVISED TO CONSULT WITH AN ATTORNEY BEFORE EXECUTING IT AND I HAVE DONE SO OR, AFTER CAREFUL READING AND CONSIDERATION I HAVE CHOSEN NOT TO DO SO OF MY OWN VOLITION;
- (v) I HAVE HAD AT LEAST 21 DAYS FROM THE DATE OF MY RECEIPT OF THIS GENERAL RELEASE AND WAIVER SUBSTANTIALLY IN ITS FINAL FORM ON \_\_\_\_\_, \_\_\_\_\_ TO CONSIDER IT AND THE CHANGES MADE SINCE THE \_\_\_\_\_, \_\_\_\_\_ VERSION OF THIS GENERAL RELEASE AND WAIVER ARE NOT MATERIAL AND WILL NOT RESTART THE REQUIRED 21-DAY PERIOD;
- (vi) I UNDERSTAND THAT I HAVE SEVEN DAYS AFTER THE EXECUTION OF THIS GENERAL RELEASE AND WAIVER TO REVOKE IT AND THAT THIS GENERAL RELEASE AND WAIVER SHALL NOT BECOME EFFECTIVE OR ENFORCEABLE UNTIL THE REVOCATION PERIOD HAS EXPIRED;
- (vii) I HAVE SIGNED THIS GENERAL RELEASE AND WAIVER KNOWINGLY AND VOLUNTARILY AND WITH THE ADVICE OF ANY COUNSEL RETAINED TO ADVISE ME WITH RESPECT TO IT; AND
- (viii) I AGREE THAT THE PROVISIONS OF THIS GENERAL RELEASE AND WAIVER MAY NOT BE AMENDED, WAIVED, CHANGED OR MODIFIED EXCEPT BY AN INSTRUMENT IN WRITING SIGNED BY AN AUTHORIZED REPRESENTATIVE OF THE COMPANY AND BY ME.

DATED AS OF \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_  
John Jacobs



October 10, 2017

Jeffrey M. Dayno, M.D.  
1501 Foxbury Road  
Maple Glen, PA 19002

Dear Jeff:

On behalf of Harmony Biosciences, LLC (“Harmony Biosciences” or the “Company”) I am pleased to extend an offer of employment with the Company as Executive Vice President and Chief Medical Officer. Except for business travel on behalf of the Company, you will work out of the Company’s Philadelphia Regional Office and other Company venues. This position will report to CEO, Bob Repella.

Your start date will be mutually determined but we anticipate it to be on or around November 13, 2017. We are excited about the possibility of you joining our team at Harmony Biosciences and hope you will accept our offer to join us in executing our growth plans for the Company.

The terms of your employment offer are outlined below:

- Bi-monthly base pay of 16,666.66, which when annualized, is equivalent to a base salary of \$400,000 per year.
- Participation (pro-rated for the calendar year in which your actual start date occurs) in the Harmony Biosciences, LLC Performance Bonus Plan at up to 50% of your base salary based on Company and individual achievement. Your bonus will be based on your performance meeting established individual goals and objectives to support the growth strategy of the Company, as well as the Company’s overall performance.
- Equity in the Company’s parent company, Harmony Biosciences II, Inc. (“Parent”) – 850,000 stock options for Parent common stock equal at an exercise price to the greater of \$1.00 and the fair market value per share of common stock as of your start date, to be determined by the Parent’s Board of Directors or its Compensation Committee, if applicable. Your Stock Option Agreement shall provide that these stock options (a) time vest at a rate of 20% per annum on each of the first five (5) anniversaries of your start date (provided that you remain an employee in good standing of the Company as of each such anniversary) and (b) accelerate vest upon a Change in Control (as defined in the Parent’s Equity Incentive Plan) provided that you remain an employee in good standing of the Company on the date of such Change in Control.

- In consideration of the money you will leave behind at your current employer for annual bonus and LTI you will receive a sign-on bonus of \$150,000 (subject to applicable tax and other withholding), paid to you in two installments. The first will be 50% (\$75,000) and paid no later than 12/31/2017. The second will be 50% (\$75,000) and paid no later than 12/31/2018. Both payments require that you are an active employee in good standing at the time of payment. If you leave the company for any reason within 12 months after receiving the first payment or 6 months after receiving the second sign-on bonus payment, you must pay back the full pre-tax amount of that payment to Harmony Biosciences.
- As a full-time Company employee, you will accrue paid vacation and sick leave. Vacation will accrue at a rate of 1.25 days per month, or 15 days per year.
- As a full-time employee of the Company, except as expressly provided for above, you are eligible to participate in the provided Harmony Biosciences, LLC Employee Benefit Plans.
- This offer is contingent upon successful completion of Harmony's pre-employment process.

You will devote all of your time and attention to the Company (including, but not limited to, its business, operations and success) and shall not compete with the Company in any way during your employment.

This offer of employment, if not previously accepted by you, will expire ten days after the date first set forth above. This offer of employment does not represent an employment contract. Just as you retain the right to resign, with or without notice or cause, Harmony Biosciences has the same right with respect to termination of your employment. You will be an employee at will, and your employment is for no definite term, regardless of any other oral or written statement by an Harmony Biosciences offer or representative, with the exception of an express written employment contract signed by the CEO, President or Chief Legal Officer of the Company. Notwithstanding anything in this offer of employment to the contrary, if your actual start date does not occur on or prior to November 13, 2017, this offer of employment will be null and void in its entirety (even if previously accepted by you.)

If you understand and accept these terms, please sign and return one copy of this offer letter to me. We would love to have you join Harmony Biosciences and be a part of building a great company. Should you have any questions regarding this offer, please feel free to contact me at 610 368 1337.

Sincerely,



Nancy Lauby  
Human Resources

Agreed to and Accepted by:



---

Jeffrey Dayno, M.D.

10/12/2017  
Date



September 8, 2017

Mr. Andrew T. Serafin  
5148 W. Winnemac Avenue  
Chicago, Illinois 60630

Dear Andrew:

On behalf of Harmony Biosciences, LLC (“Harmony Biosciences” or the “Company”), I am pleased to extend an offer of employment with the Company as Senior Vice President, Business Development Strategy. Except for business travel on behalf of the Company, you will work out of the Company’s offices in the Chicagoland area and other Company venues. This position will report to the Company’s Chief Executive Officer or his designee.

Your start date will be mutually determined but we anticipate it to be on or around September 16, 2017. We are excited about the possibility of you joining our team at Harmony Biosciences and hope you will accept our offer to join us in executing our growth plans for the Company.

The terms of your employment offer are outlined below:

1. Bi-monthly base pay of \$12,500 which, when annualized, is equivalent to a base salary of \$300,000 per year. We hope to have payroll in place for a September 30<sup>th</sup> payroll. If not, we will have payroll in place as soon as possible thereafter. Your first payroll date will occur when we have payroll in place.
2. Participation (pro-rated for the calendar year in which your actual start date occurs) in the Harmony Biosciences, LLC Performance Bonus Plan at up to 40% of your base salary based on Company and individual achievement. Your bonus will be based on your performance meeting established individual goals and objectives to support the growth strategy of the Company, as well as the Company’s overall performance.
3. Equity in the Company’s parent company, Harmony Biosciences II, Inc. (“Parent”) - stock options for 1,000,000 shares of Parent common stock (based upon an assumption of a \$270 million third party equity financing) at an exercise price equal to the greater of \$1.00 and the fair market value per share of common stock as of your grant date (which will be the later of (a) your start date or (b) the day after the closing of the Company’s upcoming third party equity financing), to be determined by the Parent’s Board of Directors or its Compensation Committee, if applicable.

Harmony Biosciences, LLC 1033 Skokie Boulevard, Suite 600 · Northbrook, IL 60062



4. As a full-time Company employee, you will accrue paid vacation and sick leave. Vacation will accrue at a rate of 1.25 days per month, or 15 days per year.
5. In addition, in consideration, in part, for your excellent work in connection with the Wakix deal over the last several months and your expected, continued excellent work with respect to a successful implementation of the Company's operations and activities over the next several months, you will be eligible to receive a special one-time bonus payable at the end of 2017 or the beginning of 2018 (provided that you remain an active employee in good standing with the Company on the date of payment) in an amount of up to \$150,000 (subject to applicable tax and other withholding), as determined by the Company's Chief Executive Officer.

This offer is contingent upon successful completion of Harmony's pre-employment process.

You will devote all of your time and attention to the Company (including, but not limited to, its business, operations and success) and shall not compete with the Company in any way during your employment.

As a full-time employee of the Company, except as expressly provided for above, you are eligible to participate in the provided Harmony Biosciences, LLC Employee Benefit Plans.

This offer of employment, if not previously accepted by you, will expire ten days after the date first set forth above. This offer of employment does not represent an employment contract. Just as you retain the right to resign, with or without notice or cause, Harmony Biosciences has the same right with respect to termination of your employment. You will be an employee at will, and your employment is for no definite term, regardless of any other oral or written statement by any Harmony Biosciences officer or representative, apart from an express written employment contract signed by the CEO, President or Chief Legal Officer of the Company. Notwithstanding anything in this offer of employment to the contrary, if your actual start date does not occur on or prior to October 2, 2017 this offer of employment will be null and void in its entirety (even if previously accepted by you).

If you understand and accept these terms, please sign and return one copy of this offer letter to me. We would love to have you join Harmony Biosciences and be a part of building a great company. Should you have any questions regarding this offer, please feel free to contact me at 847-715-0611.

Sincerely,

Anna Fenkanyn  
Human Resources

Harmony Biosciences, LLC 1033 Skokie Boulevard, Suite 600 · Northbrook, IL 60062





Agreed to and Accepted by:

A handwritten signature in black ink that reads 'Andrew T. Serafin'.

Andrew T. Serafin

09-18-17

Date

Harmony Biosciences, LLC 1033 Skokie Boulevard, Suite 600 · Northbrook, IL 60062



September 29, 2018

John M. Vittoria  
18 Powderhorn Road  
Patterson, NY 12563

Dear John:

On behalf of Harmony Biosciences, LLC (“Harmony Biosciences,” “Harmony” or the “Company”), I am pleased to extend an offer of employment with the Company as Chief Financial Officer (CFO). Except for business travel on behalf of the Company, you will work primarily out of the Company’s Plymouth Meeting headquarters office and such other Company venues from time-to-time as business needs dictate. This position will report to the Chief Executive Officer (CEO).

Your start date will be mutually determined but we anticipate it to be on or around November 12, 2018 (the “Start Date”). We are excited about you joining our team at Harmony and hope you will accept our offer to join us in executing our growth plans for the Company.

The terms of your employment offer are outlined below:

- Bi-monthly base pay of \$12,500 which, when annualized, is equivalent to a base salary of \$300,000 per year.
- Participation (pro-rated for the calendar year in which your actual start date occurs) in the Harmony Biosciences, LLC Performance Bonus Plan at up to forty percent (40%) of your base salary based on Company and individual achievement. Your bonus will be based on your performance meeting established individual goals and objectives to support the growth strategy of the Company, as well as the Company’s overall performance.
- Equity in the Company’s parent company, Harmony Biosciences II, Inc. (“Parent”) in the amount of 400,000 stock options for Parent common stock with an exercise price equal to the greater of \$1.00 and the fair market value per share of common stock as of your start date, to be determined by the Parent’s Board of Directors or its Compensation Committee, if applicable.
- In consideration for your relocation from New York to the Philadelphia area to accept this role, the Company will pay you a one-time lump sum payment of \$45,000 (subject to customary tax withholdings, as applicable) (the “Relocation Payment”), payable on or

Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA 19462

before the November 30, 2018 payroll, provided that, you shall be required to pay back to the Company an amount equal to the Relocation Payment in the event you voluntarily terminate your employment prior to the one-year anniversary of the Start Date.

- If your employment is terminated by Company without legal cause, the Company shall (i) pay to you an aggregate amount equal to your annual base salary within thirty (30) days after the date of termination (subject to customary tax withholdings, as applicable), and (ii) for the twelve (12) month period following the date of termination (the "Coverage Period"), reimburse you for the Company's share of premiums for the continuation of health coverage (on a basis consistent with your elections as of immediately prior to the termination date) under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), for you and your eligible dependents, provided however, Harmony can in its sole discretion, pay directly to you the Company's share of premiums in a single lump sum payment for the entire Coverage Period.
- As a full-time Company employee, you will accrue paid vacation and sick leave. Vacation will accrue at a rate of 1.25 days per month, or 15 days per year.
- As a full-time employee of the Company, except as expressly provided for above, you are eligible to participate in the provided Harmony Biosciences, LLC Employee Benefit Plans.
- This offer is contingent upon successful completion of Harmony's pre-employment process, including background verification and drug testing. By signing and returning a copy of this offer letter to me, you expressly consent to such background verification (including dates of employment and previous employer salary) and other pre-employment processes. In addition, you will be required to sign a non-competition and confidentiality agreement.

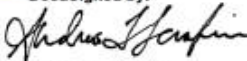
You will devote all of your time and attention to the Company (including, but not limited to, its business, operations and success) and shall not compete with the Company in any way during your employment.

This offer of employment, if not previously accepted by you, will expire ten (10) days after the date first set forth above. This offer of employment does not represent an employment contract. Just as you retain the right to resign, with or without notice or cause, Harmony Biosciences has the same right with respect to termination of your employment. You will be an employee-at-will, and your employment is for no definite term, regardless of any other oral or written statement by any Harmony Biosciences officer or representative, with the exception of an express written employment contract signed by the President or CEO of the Company. Notwithstanding anything in this offer of employment to the contrary, if your actual start date does not occur on or prior to December 12, 2018, this offer of employment will be null and void in its entirety (even if previously accepted by you).

Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA 19462

If you understand and accept these terms, please sign and return one copy of this offer letter to me. We would love to have you join Harmony Biosciences and be a part of building a great company. Should you have any questions regarding this offer, please feel free to contact me at (847) 715-0597.

Sincerely,

DocuSigned by:  
  
218FF88011154BB...

Andrew Serafin  
SVP—Business Affairs & Human Resources

Agreed to and Accepted by:

DocuSigned by:  
  
7A5224A59451420...

9/30/2018 11:52:37 AM EDT

---

John M. Vittoria

---

Date

Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA 19462

**FORM OF INDEMNIFICATION AGREEMENT**

This Indemnification Agreement (“Agreement”) is made as of \_\_\_\_\_, 2020 by and between Harmony Biosciences Holdings, Inc., a Delaware corporation (the “Company”), and \_\_\_\_\_, [a member of the Board of Directors / an officer] of the Company (“Indemnitee”). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering the subject matter of this Agreement.

**RECITALS**

WHEREAS, the Board of Directors of the Company (the “Board”) believes that highly competent persons have become more reluctant to serve publicly held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Bylaws of the Company (the “Bylaws”) require indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the “DGCL”). The Bylaws and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification may increase the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation of the Company (the "Certificate of Incorporation"), the Bylaws, and any resolutions adopted pursuant thereto, as well as any rights of Indemnitees under any directors' and officers' liability insurance policy, and this Agreement shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation, Bylaws and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve or continue to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve as a [director] [officer] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Bylaws, and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an [officer] [director] of the Company, as provided in Section 16 hereof.

Section 2. Definitions. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the Surviving Entity) more than 50% of the combined voting power of the voting securities of the Surviving Entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(d) "Surviving Entity" shall mean the surviving entity in a merger or consolidation or any entity that controls, directly or indirectly, such surviving entity.

(c) "Corporate Status" describes the status of a person who is or was a director, trustee, partner, managing member, officer, employee, agent or fiduciary of the Company or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of the Company.

(d) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(f) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees and other costs of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements, obligations or expenses of the types customarily incurred in connection with, or as a result of, prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a deponent or witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, (ii) expenses incurred in connection with recovery under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee is ultimately determined to be entitled to such indemnification, advancement or Expenses or insurance recovery, as the case may be, and (iii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, the Certificate of Incorporation, the Bylaws or under any directors' and officers' liability insurance policies maintained by the Company, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable in the good faith judgment of such counsel shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.



(g) “Independent Counsel” shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term “Independent Counsel” shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee’s rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term “Proceeding” shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, regulatory or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of Indemnitee’s Corporate Status, by reason of any action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee’s part while acting pursuant to Indemnitee’s Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to “other enterprise” shall include employee benefit plans; references to “fines” shall include any excise tax assessed with respect to any employee benefit plan; references to “serving at the request of the Company” shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner Indemnitee reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Company” as referred to in this Agreement.

Section 3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee’s behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that

Indemnitee's conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of the Company's stockholders or disinterested directors or applicable law.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court (as hereinafter defined) or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness, is or was made (or asked) to respond to discovery requests in any Proceeding, or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

Section 7. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) by reason of Indemnitee's Corporate Status.

(b) For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 9. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision;

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) such payment arises in connection with any mandatory counterclaim or cross claim brought or raised by Indemnitee in any Proceeding (or any part of any Proceeding), or (iii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board as provided in Section 9(c), and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) by the Company pursuant to this Section 10, if and only to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

(c) The Company shall not settle any Proceeding (in whole or in part) if such settlement would impose any Expense, judgment, liability, fine, penalty or limitation on Indemnitee in respect of which Indemnitee is not entitled to be indemnified hereunder without Indemnitee's prior written consent, which shall not be unreasonably withheld.

Section 12. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by or on behalf of Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such

objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(c) If the Company disputes a portion of the amounts for which indemnification is requested, the undisputed portion shall be paid and only the disputed portion withheld pending resolution of any such dispute.

### Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders

pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnatee to indemnification or create a presumption that Indemnatee did not act in good faith and in a manner which Indemnatee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnatee had reasonable cause to believe that Indemnatee's conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnatee shall be deemed to have acted in good faith if Indemnatee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnatee by the directors or officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser, financial advisor or other expert selected with reasonable care by or on behalf of the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnatee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnatee for purposes of determining the right to indemnification under this Agreement.

#### Section 14. Remedies of Indemnatee.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnatee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the second to last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnatee is entitled to indemnification, or (vi) the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any

litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a). The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by or on behalf of Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.



(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement (i) shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise and (ii) shall be interpreted independently of, and without reference to, any other such rights to which Indemnitee may at any time be entitled. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation, the Bylaws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment made by the Company under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 16. Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a [director] [officer] of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding (including any appeal thereof) commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives. The Company shall require and shall cause any successor (whether direct or indirect by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to, by written agreement, expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

Section 17. Severability. Nothing in this Agreement is intended to require or shall be construed as requiring the Company to do or fail to do any act in violation of applicable law. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the Bylaws, any directors' and officers' insurance maintained by the Company and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 20. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 21. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to

c/o Harmony Biosciences Holdings, Inc.  
630 W. Germantown Pike, Suite 215  
Plymouth Meeting, Pennsylvania 19462  
Attn: General Counsel  
Email: swisdo@harmonybiosciences.com

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in

light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 23. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Court of Chancery of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or Proceeding in the Delaware Court and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 24. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 25. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

HARMONY BIOSCIENCES  
HOLDINGS, INC.

INDEMNITEE

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Office: \_\_\_\_\_

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_

[Signature Page to Indemnification Agreement]

**HARMONY BIOSCIENCES, LLC**

**SEPARATION PLAN**

As Adopted Effective as of June [\*], 2020

THIS DOCUMENT CONSTITUTES THE OFFICIAL PLAN DOCUMENT  
AS WELL AS THE SUMMARY PLAN DESCRIPTION OF THIS PLAN

**HARMONY BIOSCIENCES, LLC  
SEPARATION PLAN AND SUMMARY PLAN DESCRIPTION**

**Table of Contents**

<b>Section</b>	<b>Page Number</b>
I. Purpose of the Plan	1
II. Eligibility and Participation	1
III. Severance Benefits	2
IV. Participant Obligations	3
V. Claims	6
VI. Administration	7
VII. Taxes	9
VIII. Term of Plan; Amendment and Termination of Plan	10
IX. Miscellaneous	11
X. ERISA Rights	13
XI. ERISA Information	14
XII. Definitions	15
Exhibit A - Release	

**HARMONY BIOSCIENCES, LLC**  
**SEPARATION PLAN AND SUMMARY PLAN DESCRIPTION**

**I. PURPOSE OF PLAN**

The Company has established the Plan:

- (a) to provide the terms and conditions relating to a Participant's eligibility for certain benefits upon a Termination in connection with a Change in Control;
- (b) to recruit and retain certain highly qualified individuals as Employees; and
- (c) to maintain the focus of Employees on the business of the Company or the Parent and to mitigate the distractions caused by the possibility that the Employee's employment may be terminated or that the Company or the Parent may be the target of an acquisition.

The Plan is intended to be an employee welfare benefit plan within the meaning of Section 3(1) of ERISA. Further, this Plan is intended constitute a severance pay plan within the meaning of Department of Labor Regulation Section 2510.3-2(b), and it is intended that all payments made under the Plan be deductible by the Company under Code Section 162(a).

Terms in initial capital letter will have the meaning assigned to them in Section XII of the Plan.

This document is the official plan document and has been drafted so that its contents and wording also will be a summary plan description (or SPD) (as required and defined by ERISA).

**II. ELIGIBILITY AND PARTICIPATION**

**2.1 Eligibility.** All Employees are eligible to participate in the Plan.

**2.2 Participation.** Participants are those Employees designated by the Administrator in its sole discretion to participate in the Plan; *provided, however*, that the Administrator is not permitted to designate an Employee as a new Participant following a Change in Control Date. An Employee who becomes a Participant will remain a Participant until the earlier of the date the Plan is terminated or the date all obligations of the Company and the Participant under the Plan are fulfilled. Participation will be evidenced by the Employee's acknowledgment of his or her designation as a Participant in the form specified by the Administrator.



### III. SEVERANCE BENEFITS

**3.1 Severance Benefits.** If a (I) Termination occurs during the Change in Control Protection Period, (II) the Participant has not been offered a Comparable Position, and (III) the Participant complies with the requirements of Section 4 below, the Participant will be eligible to receive the benefits set forth in this Section 3. A Participant's benefits under this Section 3 will be in lieu of any benefits under an employment agreement between the Participant and the Company or the Parent, as applicable, except where such payment of a lump sum hereunder would result in a violation of Section 409A of the Code, to the extent applicable, in which case benefits under this Section 3 will be offset on a dollar for dollar basis for any benefits paid under the employment agreement and any excess payable under this Plan will be paid in a lump sum as provided under this Section 3. Determinations with respect to Code Section 409A (and offset described) will be made by the Administrator in its sole discretion.

**(a) Severance Pay.** A lump sum cash payment equal to the sum of the following:

- (i) an amount equal to a pro rata portion of the annual bonus which would have been paid for the year in which the Termination Date occurs, with the amount determined based on 100% of the Participant's "target" bonus for the calendar year of the Termination Date, multiplied by a fraction, the numerator of which is the number of calendar days in the year of the Termination Date prior to the Termination Date and the denominator is 365; provided, however, if the Participant is on an active performance management plan or a performance improvement plan, the amount of the pro rata portion of the annual bonus may be reduced in the sole discretion of the Administrator; plus
- (ii) an amount equal to six (6) months of the Terminated Participant's Salary; plus
- (iii) the Change in Control Health Benefit.

**(b) Outplacement Assistance.** Outplacement assistance as determined in the discretion of the Administrator, to be provided by a vendor selected by the Company in accordance with the terms of the applicable program then being offered by the Company. Outplacement assistance must commence within forty-five (45) days of the expiration of the Revocation Period (as defined in Section 3.5 below), and must be completed before the end of the calendar year following the year in which the Termination Date occurred.

**3.2. Payment of Severance Pay to Beneficiaries.** If a Terminated Participant dies after his or her Termination during the Change in Control Protection Period, all Severance Pay that would have been paid to the Terminated Participant under this Section 3 but for his or her death, will be paid to the Terminated Participant's Beneficiary in a single lump sum payment within sixty (60) days following the Participant's death.

- 3.3. Equity Plans.** The Severance Benefits are in addition to the benefits, if any, under any equity incentive plan, program, or arrangement, which benefits will be determined solely in accordance with any such equity incentive plan, program, or arrangement.
- 3.4. Payment of Severance Pay.** Severance Pay under this Section 3 will be paid in the form determined in the sole discretion of the Administrator, which form may include (1) a single lump sum payment; or (2) in equal installments in accordance with the Company's regular payroll practice. Severance Pay shall begin to be paid on the first payroll period following the expiration of the time period for the Participant to revoke his or her execution of the Release (as defined in Section 4.1 below) as specified in the Release (the "Revocation Period"); provided, however, that in no event will the Severance Pay begin to be paid later than the sixtieth (60<sup>th</sup>) day following the Termination Date.

#### IV. PARTICIPANT OBLIGATIONS

- 4.1 Waiver and Release.** As a condition for receiving Severance Benefits under this Plan, a Terminated Participant must timely execute (and not revoke) and deliver to the Company a waiver and release substantially in the form attached to the Plan as Exhibit A (the "Release") within the time period specified in the Release. The Release, in final executable form as determined by the Administrator, will be provided to the Terminated Participant by the Company no later than five (5) days after the Termination Date.
- 4.2 Noncompetition.** At all times during a Participant's service with the Company or the Parent and for twelve (12) months following the Participant's Termination Date, the Participant shall not, directly or indirectly, engage in a Competitive Activity.
- 4.3 Nonsolicitation.** At all times during a Participant's service with the Company or the Parent and for twelve (12) months following the Participant's Termination Date, the Participant shall not directly or indirectly through another entity (a) induce or attempt to induce any employee of the Parent or the Company to leave the employ or service of the Parent or the Company, (b) induce or attempt to induce any customer, supplier, licensee, or other business relation of the Parent or the Company to cease doing business with the Parent or the Company, or (c) usurp any business opportunity presented to the Parent or the Company or which the Parent or the Company was, in good faith, considering prior to the Termination Date.
- 4.4 Confidentiality.** At all times prior to and following a Participant's Termination Date, the Participant shall not disclose to anyone or make use of any trade secret or proprietary or confidential information of the Company or the Parent, including trade secret or proprietary or confidential information of any customer or client or other entity to which the Company or the Parent owes an obligation not to disclose such information, which he or she acquires during his or her service with the Company or the Parent, including, but not limited to, records kept in the ordinary course of business, except:

- (a) as may be required or appropriate in connection with his or her work as an employee of the Company or the Parent;
  - (b) when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or the Parent or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order him or her to divulge, disclose, or make accessible such information, or in connection with whistleblower protections afforded under applicable Federal or state statute; (which shall not require prior notice to the Company), provided that neither the Company nor the Parent waives any attorney-client privilege;
  - (c) with respect to confidential information that becomes generally known to the public or trade without his or her violation of this Section 4.4; or
  - (d) to the Participant's spouse and/or his or her personal tax and financial advisors as reasonably necessary or appropriate to advance the Participant's tax, financial, and other personal planning (each an "Exempt Person"), *provided, however*, that any disclosure or use of any trade secret or proprietary or confidential information of the Company or the Parent by an Exempt Person shall be deemed to be a breach of this Section 4.4 by the Participant.
- 4.5 Non-Disparagement.** At all times prior to and following a Participant's Termination Date, the Participant shall not make any statements or express any views that disparage the business reputation or goodwill of the Parent or the Company, any officers, directors or managers thereof or any products, whether orally, in writing, or in any electronic medium (including, without limitation, on any social media or similar platform).
- 4.6 Resignation as Officer and Manager.** The Participant shall be deemed to resign as (a) an officer of the Company or the Parent, (b) a member of the board and similar body of the Company or the Parent, and (c) any trustee (or similar position) of any Company or Parent benefit plan, program, or trust as of his or her Termination Date.
- 4.7 Return of Company Property.** On, before, or immediately following a Participant's Termination Date, a Participant shall return all property of the Company or the Parent in his or her possession, including, but not limited to, all computer equipment (hardware and software), telephones, facsimile machines, Blackberrys/smart phones/PDAs, and other communication devices, credit cards, office keys, security access cards, badges, identification cards, and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company or the Parent, its and their customers and clients, or its and their prospective customers and clients.
- 4.8 Cooperation.** A Participant's entitlement to benefits under this Plan is conditioned on the Participant cooperating to the extent reasonably requested, as determined by the Administrator, to effect the applicable Change in Control. Without limiting the foregoing, following a Participant's Termination Date, the Participant shall give his or her assistance

and cooperation willingly, upon reasonable advance notice with due consideration for his or her other business or personal commitments, in any matter relating to his or her position with the Company or the Parent or his or her expertise or experience as the Company or the Parent may reasonably request, including his or her attendance and truthful testimony where deemed appropriate by the Company or the Parent, with respect to any investigation or the Company's or the Parent's defense or prosecution of any existing or future claims or litigation or other proceedings relating to matters in which he or she was involved or potentially had knowledge by virtue of his or her service with the Company or the Parent. In no event will his or her cooperation materially interfere with his or her services for a subsequent employer or other similar service recipient. The Company agrees that (a) it will promptly reimburse the Participant for his or her reasonable and documented expenses in connection with his or her rendering assistance and/or cooperation under this Section 4.8, upon his or her presentation of documentation for such expenses and (b) the Participant will be reasonably compensated for any continued material services as required under this Section 4.8.

- 4.9 Enforcement of Section 4.** If a Terminated Participant materially violates any provision of this Section 4, he or she shall immediately forfeit any right, title and interest to any Severance Benefits that have not yet been paid or provided, and the Terminated Participant shall be required to immediately repay to the Company on demand a cash amount equal to the gross amount of the Severance Benefits that he or she has already received or that were provided.
- 4.10 Enforcement of Noncompetition, Nonsolicitation and Confidentiality Covenants.** In addition to Section 4.9 above, if a Terminated Participant violates or threatens to violate any provision of this Section 4, the Company shall not have an adequate remedy at law. Accordingly, the Company shall not be required to pay or provide (and the Participant shall forfeit without consideration) any amounts or Severance Benefits under Section 3 above, and the Company shall be entitled to such equitable and injunctive relief as may be available to restrain the Terminated Participant and any business, firm, partnership, individual, corporation, or entity participating in the breach or threatened breach from the violation of the provisions of this Section 4 (without having to post a bond or other security or proving inadequacy of monetary damages). Nothing in the Plan shall be construed as prohibiting the Company from pursuing any other remedies available at law or in equity for breach or threatened breach of this Section 4, including the recovery of damages.
- 4.11 Protected Activity.** Nothing in this Plan shall preclude a Participant from: (a) engaging in concerted, protected activity under the National Labor Relations Act (such as discussing wages and terms and conditions of employment with co-workers) to the extent that the Participant is a non-managerial, non-supervisory employee; (b) taking any lawful action or making any disclosure to the extent protected or required by applicable law; or (c) communicating with, providing information to, testifying before, or otherwise assisting any governmental agency, official, or body with respect to a possible violation of any law, rule, or regulation. Without prior authorization from the Company's Legal Department, however, the Company does not authorize the Participant to disclose to anyone a communication that is covered by the Company's attorney-client privilege.

**4.12 Blue Pencil.** If, at any time, the provisions of this Section 4 are determined to be invalid or unenforceable under any applicable law, by reason of being vague or unreasonable as to area, duration or scope of activity with respect to a Participant, this Plan will be considered divisible and may become and be immediately amended (or reformed) to only such area, duration and scope of activity as is determined to be reasonable and enforceable by the court or other body having jurisdiction over the matter, and the Participant and the Company agree that this Plan as so amended will be valid and binding as though any invalid or unenforceable provision had not been included herein.

## V. CLAIMS

**5.1 Claims Procedure.** If any Participant or Beneficiary, or his or her legal representative (the "Claimant"), has a claim for benefits under the Plan which is not being paid, the Claimant may file a written claim with the Administrator setting forth the amount and nature of the claim, supporting facts, and the Claimant's address. Written notice of the disposition of a claim by the Administrator will be furnished to the Claimant within ninety (90) days after the claim is filed. If the Administrator determines that special circumstances require an extension of time for processing the claim, the Administrator may take up to an additional ninety (90) days to process the claim, provided that written notice of the extension is furnished to the Claimant prior to the expiration of the initial ninety (90) day period, which notice will indicate the special circumstances requiring the extension and the date by which the Plan expects to render a decision.

If the claim is denied, the Administrator will provide written or electronic notification of the determination to the Claimant, which notification shall set forth (a) the reasons for the denial; (b) reference to the pertinent provisions of the Plan on which the denial is based; (c) a description of any additional material or information necessary for the Claimant to perfect the claim and an explanation of why the material or information is necessary; and (d) a description of the Plan's claim review procedure, and the time limits applicable to those procedures.

**5.2 Claims Review Procedure.** If a Claimant whose claim has been denied wishes further consideration of his or her claim, he or she may request the Administrator to review the claim in a written request for review, which must be filed with the Administrator no later than sixty (60) days after receipt of the written notification of disposition provided for in Section 5.1 above. As part of the review, the Claimant will have the opportunity to submit written comments, documents, records, and other information relating to the claim for benefits; will be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefit. The Administrator will fully and fairly review the matter and will take into account all comments, documents, records, and other information submitted by the Claimant relating to the claim, without regard to whether it was submitted or considered in the initial benefit determination. The Administrator will notify the Claimant of its determination on review within sixty (60) days after receipt of the Claimant's request for review. If the Administrator determines that special circumstances require an extension of time for processing the claim, the Administrator may take up to an additional sixty (60) days to

process the claim, provided that written notice of the extension is furnished to the Claimant prior to the expiration of the initial sixty (60) day period, which notice will indicate the special circumstances requiring the extension and the date by which the Plan expects to render a decision.

The Administrator will provide written or electronic notification of its determination on review to the Claimant, which notification will set forth (a) the reasons for the denial; (b) reference to the pertinent provisions of the Plan on which the denial is based; and (c) a description of the dispute resolution procedures offered by the Plan (as described in Section 5.3 hereof).

**5.3 Dispute Resolution.** Any disputes arising under or in connection with the Plan (other than proceedings for injunctive relief with respect to or in connection with Section 4 above) shall be resolved by binding arbitration, to be held in the Greater Philadelphia, Pennsylvania area or in any other location mutually agreed to by the Company and the applicable Participant in accordance with the rules and procedures of the American Arbitration Association. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. A Participant must exhaust the claims and appeals procedures set forth in Sections 5.1 and 5.2 above before requesting binding arbitration. A request for binding arbitration to resolve a dispute must be made no later than ninety (90) days following the Administrator's final determination on review pursuant to Section 5.2 hereof.

**5.4 Reimbursement of Expenses.** If there is any dispute between the Company and a Participant with respect to a claim under the Plan, the Company will reimburse the Participant for all reasonable fees, costs and expenses incurred by the Participant with respect to the disputed claim; *provided, however*, that (i) the Participant is the prevailing party with respect to the disputed claim or (ii) the disputed claim is settled in the Participant's favor.

## VI. ADMINISTRATION

**6.1 Responsibility.** The Administrator shall have the responsibility, in its sole discretion, to control, operate, manage and administer the Plan in accordance with its terms.

**6.2 Authority of the Administrator.** The Administrator shall have the maximum discretionary authority permitted by law that may be necessary to enable it to discharge its responsibilities with respect to the Plan, including, but not limited to, the following:

- (a) to determine eligibility for participation in the Plan and designate Employees as Participants;
- (b) to determine the occurrence of a Change in Control, whether a Termination was for Cause or Good Reason or other determinations hereunder;
- (c) to determine or calculate a Participant's Severance Benefits;

- (d) to correct any defect, supply any omission, or reconcile any inconsistency in the Plan in such manner and to such extent as it shall deem appropriate in its sole discretion to carry the same into effect;
  - (e) to issue administrative guidelines as an aid to administer the Plan and make changes in the guidelines as it from time to time deems proper;
  - (f) to make rules for carrying out and administering the Plan and make changes in the rules as it from time to time deems proper;
  - (g) to the extent permitted under the Plan, grant waivers of Plan terms, conditions, restrictions, and limitations; and
  - (h) to take any and all other actions it deems necessary or advisable for the proper operation or administration of the Plan.
- 6.3 Action by the Administrator.** The Administrator may act at a meeting (whether in person or by telephone or video conference) only by a vote or determination of a majority of its members. In addition, any vote or determination of the Administrator may be made, without a meeting, by a writing or writings signed by all of the members of the Administrator. In addition, the Administrator may authorize any one or more of its members to execute and deliver documents on behalf of the Administrator.
- 6.4 Delegation of Authority.** The Administrator may delegate to one or more of its members, or to one or more agents, such administrative duties as it may deem advisable; *provided, however,* that any delegation shall be in writing. In addition, the Administrator, or any person to whom it has delegated duties, may employ one or more persons to render advice with respect to any responsibility the Administrator or they may have under the Plan. The Administrator may employ legal or other counsel, consultants, and agents as it may deem desirable for the administration of the Plan and may rely upon any opinion or computation received from any counsel, consultant or agent so engaged. Expenses incurred by the Administrator in the engagement of any counsel, consultant, or agent will be paid by the Company or the Parent whose employees have benefited from the Plan, as determined by the Administrator.
- 6.5 Determinations and Interpretations by the Administrator.** All determinations and interpretations made by the Administrator shall be in the sole discretion of the Administrator and shall be binding and conclusive to the maximum extent permitted by law on all Participants and their heirs, successors, and legal representatives.
- 6.6 Information.** The Company shall furnish to the Administrator in writing all information the Administrator may deem necessary, desirable or appropriate for the exercise of its powers and duties in the administration of the Plan. Such information may include, but shall not be limited to, the full names of all Participants, their earnings, and their dates of birth, employment, retirement or death. Such information shall be conclusive for all purposes of the Plan, and the Administrator shall be entitled to rely thereon without any investigation thereof.

- 6.7 Liability.** The Administrator (including, if applicable, the members of the Parent Board) shall not be liable, and no Employee providing services to the Company or the Parent shall be liable, for any act or failure to act hereunder, except in circumstances involving his or her bad faith, gross negligence, or willful misconduct, or liable for any act or failure to act hereunder by any other member or employee or by any agent to whom duties in connection with the administration of the Plan have been delegated.
- 6.8 Indemnification.** The Company shall indemnify the Administrator (including, if applicable, the members of the Parent Board) and any agent of the Administrator who is an Employee providing services to the Company or the Parent, against any and all liabilities or expenses to which they may be subjected by reason of any act or failure to act with respect to their duties on behalf of the Plan to the extent provided in the Company's governing documents and under applicable law, except in circumstances involving the person's bad faith, gross negligence, or willful misconduct.

## VII. TAXES

- 7.1 Withholding Taxes.** The Company and the Parent shall be entitled to withhold from any and all payments made under the Plan all federal, state, local, and/or other taxes which the Company determines are required to be so withheld from such payments or by reason of any other payments made to or on behalf of the Participant or for his or her benefit hereunder.
- 7.2 Golden Parachute Excise Tax.** In the event that a Participant becomes subject to the excise tax imposed by Code Section 4999 (the "Parachute Excise Tax") and/or the Company or the Parent would lose a tax deduction due to the imposition of Code Section 280G, any payments or benefits under the Plan will be reduced to the extent necessary to avoid the Parachute Excise Tax and/or loss of deduction, provided, that the Company may seek exemption under Code Section 280G's shareholder approval exception, subject to the cooperation of "disqualified individuals" affected under Code Section 4999.
- 7.3 Code Section 409A.** All amounts payable under this Plan are intended to comply with the "short term deferral" exception from Code Section 409A ("Section 409A") specified in Treas. Reg. §1.409A-1(b)(4) (or any successor provision) or the separation pay plan exception specified in Treas. Reg. §1.409A-1(b)(9) (or any successor provision), or both of them, and shall be interpreted in a manner consistent with those exceptions. Notwithstanding the foregoing, to the extent that any amounts payable in accordance with this Plan are subject to Section 409A, the Plan shall be interpreted and administered in such a way as to comply with the applicable provisions of Section 409A to the maximum extent possible. To the extent that the Plan is subject to Section 409A and fails to comply with the requirements of Section 409A, the Company reserves the right (without any obligation to do so) to amend, restructure, terminate, or replace the Plan in order to cause the Plan either to comply with the applicable provisions of Section 409A or not be subject to Section



409A. If payment of any amount of “deferred compensation” (as defined under Section 409A) is triggered by a separation from service that occurs while the Employee is a “specified employee” (as defined under Section 409A) with respect to Company, and if such amount is scheduled to be paid within six (6) months after such separation from service, the amount shall accrue without interest and shall be paid the first business day after the end of such six-month period, or, if earlier, within 15 days after the Participant’s death. Each payment under the Plan shall be treated as a separate payment of compensation for purposes of applying Section 409A. “Termination of employment,” “retirement,” “resignation” or words of similar import, as used in the Plan shall mean, with respect to any payments of deferred compensation subject to Section 409A of the Code, the Participant’s “separation from service” as defined in Section 409A. The Participant shall not have the ability to control, directly or indirectly, the timing of any payments of deferred compensation subject to Section 409A. Any payments that are deferred compensation subject to Section 409A, and that could occur in one of two calendar years depending on the timing of an action by a Participant, such as the delivery of a release, will always occur in the later year. A Participant shall not have the ability to select the timing or form of any payment under this Plan. Nothing in this Plan shall be construed as a guarantee of any particular tax treatment to a Participant. A Participant shall be solely responsible for the tax consequences with respect to all amounts payable under the Plan, and in no event shall the Company have any responsibility or liability if the Plan does not meet any applicable requirements of Section 409A.

- 7.4 No Guarantee of Tax Consequences.** No person connected with the Plan in any capacity, including, but not limited to, the Parent or the Company and their respective managers, officers, agents, and employees makes any representation, commitment, or guarantee that any tax treatment, including, but not limited to, federal, state, and local income, estate, and gift tax treatment, will be applicable with respect to benefits or amounts payable or provided under the Plan, or paid to or for the benefit of a Participant under the Plan, or that such tax treatment will apply to or be available to a Participant on account of participation in the Plan.

#### **VIII. TERM OF PLAN; AMENDMENT AND TERMINATION OF PLAN**

- 8.1 Term of Plan.** The Plan shall be effective as of the Effective Date and shall remain in effect until the Parent Board terminates or suspends the Plan in accordance with Section 8.3 below.
- 8.2 Amendment of Plan.** The Plan may be amended by the Parent Board at any time with or without prior notice; *provided, however*, that if the Plan is amended during the Change in Control Protection Period such amendment may not be adverse to a Participant with respect to eligibility or amount of payments or benefits hereunder without the written consent of such Participant(s).
- 8.3 Termination of Plan.** The Plan may be terminated or suspended by the Parent Board at any time with or without prior notice; *provided, however*, that the Plan shall not be terminated or suspended during the Change in Control Protection Period without the written consent of a majority of the Participants.

**8.4 No Adverse Effect.** If the Plan is amended, terminated, or suspended in accordance with Section 8.2 or 8.3 above, such action shall not adversely affect the Severance Benefits of any Terminated Participant who, at the date of such amendment, termination or suspension, is already receiving or entitled to receive Severance Benefits under the Plan.

## IX. MISCELLANEOUS

- 9.1 No Mitigation.** A Terminated Participant shall be under no obligation to seek other employment following the Termination Date and there shall be no offset against amounts due the Terminated Participant under the Plan on account of any compensation attributable to any subsequent employment.
- 9.2 Offset; No Duplication of Benefits.** Without limiting Section 3 above, and to the extent permitted by Section 409A, Severance Benefits provided hereunder shall automatically be reduced by any payment or benefit made or provided or to be made or to be provided by the Company or the Parent to the Participant pursuant to (i) the termination of employment/service provisions of any employment agreement or services arrangement between the Company or the Parent and the Participant, and (ii) any federal, state or local statute, rule, regulation or ordinance.
- 9.3 No Right, Title, or Interest in Company or Parent Assets.** Participants shall have no right, title, or interest whatsoever in or to any assets of the Company or the Parent or any investments which the Company or the Parent may make to aid it in meeting its obligations under the Plan. Nothing contained in the Plan, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind, or a fiduciary relationship between the Company or the Parent and any Participant, Beneficiary, legal representative or any other person. To the extent that any person acquires a right to receive payments from the Company or the Parent under the Plan, such right shall be no greater than the right of an unsecured general creditor of the Company or the Parent. Subject to this Section 9.3, all payments to be made hereunder shall be paid from the general funds of the Company or the Parent and no special or separate fund shall be established and no segregation of assets shall be made to assure payment of such amounts.
- 9.4 No Right to Continued Employment.** The Participant's rights, if any, to continue to serve the Company or the Parent as an employee or service provider shall not be enlarged or otherwise affected by his or her designation as a Participant under the Plan, and the Company or the Parent reserves the right to terminate the employment or service of any Employee at any time. The adoption of the Plan shall not be deemed to give any Employee, or any other individual, any right to be selected as a Participant or to continued employment or service with the Company or the Parent.
- 9.5 Governing Law.** The Plan shall be governed by and construed in accordance with the laws of Pennsylvania without reference to principles of conflict of laws, except as superseded by ERISA and other applicable federal law.

- 9.6 Severability.** If any term or condition of the Plan shall be invalid or unenforceable to any extent or in any application, then the remainder of the Plan, with the exception of such invalid or unenforceable provision, shall not be affected thereby and shall continue in effect and application to its fullest extent.
- 9.7 Incapacity.** If the Administrator determines that a Participant or a Beneficiary is unable to care for his or her affairs because of illness or accident or because he or she is a minor, any benefit due the Participant or Beneficiary may be paid to the Participant's spouse or to any other person deemed by the Administrator to have incurred expense for the Participant (including a duly appointed guardian, Administrator or other legal representative), and any such payment shall be a complete discharge of the Company's obligation hereunder.
- 9.8 Transferability of Rights.** The Plan shall be binding on and inure to the benefit of the executors, heirs, administrators, successors and assigns of a Participant and the successors and assigns of Company. The Company shall have the unrestricted right to transfer its obligations under the Plan with respect to one or more Participants to any person, including, but not limited to, any purchaser of all or any part of the Company's business. No Participant or Beneficiary shall have any right to commute, encumber, transfer or otherwise dispose of or alienate any present or future right or expectancy which the Participant or Beneficiary may have at any time to receive benefits hereunder, which benefits and the right thereto are expressly declared to be non-assignable and nontransferable, except to the extent required by law. Any attempt to transfer or assign a benefit, or any rights granted hereunder, by a Participant or the spouse of a Participant shall, in the sole discretion of the Administrator (after consideration of such facts as it deems pertinent), be grounds for terminating any rights of the Participant or Beneficiary to any portion of the Plan benefits not previously paid or provided.
- 9.9 Non-Exclusivity.** This Plan shall not prevent or limit a Participant's continuing future participation in any benefit, bonus, incentive, severance plan or arrangement provided by the Company and for which the Participant may qualify.
- 9.10 Headings.** The headings of this Plan are for convenience and reference only and do not constitute a part hereof.
- 9.11 Summary Document.** Any summary document or other Plan summary is a summary of terms only and is qualified in its entirety by the terms of this Plan and any inconsistency of such document or summary with this Plan will be interpreted in favor of the Plan.
- 9.12 Successors.** The Company shall cause any successor (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of its business and/or assets to expressly assume and agree to perform all of the Company's obligation hereunder in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

## X. ERISA RIGHTS

As a Participant in the Plan, you are entitled to certain rights and protections under ERISA, which provides that all Plan Participants shall be entitled to:

### **Receive information about your Plan and benefits.**

- Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 series) filed by the Plan with the U.S. Department of Labor, and available at the Public Disclosure Room of the Employee Benefits Security Administration.
- Obtain, upon written request to the Plan Administrator, copies of all documents governing the operation of the Plan, and copies of the latest annual report (Form 5500 series) and updated summary plan description. The Plan Administrator may make a reasonable charge for the copies.

### **Prudent actions by the Plan fiduciaries.**

In addition to creating rights for Plan participants, ERISA imposes obligations upon the people who are responsible for the operation of the Plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Plan participants and beneficiaries. No one, including your employer or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining benefits or exercising your rights under ERISA.

### **Enforce your rights.**

If your claim for a benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain periods.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of plan documents or the latest annual report from the Plan Administrator and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to \$110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator. If you have a claim for benefits that is denied or ignored, in whole or in part, you may file suit in a state or Federal court after exhausting the Plan's claims procedures. If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds that your claim is frivolous.

---

**Assistance with your questions.**

If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory, or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

**XI. ERISA INFORMATION**

Official Name of the Plan	Harmony Biosciences, LLC Separation Plan
Sponsor	Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215 Plymouth Meeting, PA 19462 (484) 539-9800
Employer Identification Number	82-1608705
Plan Number	505
Type of Plan	Employee Welfare Severance Benefit Plan
Plan Year	January 1 - December 31, with a short plan year from June [*], 2020, through December 31, 2020
Type of Administration	Employer Administered
Plan Administrator	Harmony Biosciences, LLC
Effective Date	June [*], 2020
Agent for Service of Legal Process	General Counsel Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215 Plymouth Meeting, PA 19462

## XII. DEFINITIONS

The following capitalized terms shall have the following meanings unless the context indicates otherwise as determined by the Administrator:

- 12.1 **“Administrator”** means, (a) with respect to the Key Executives, the Parent Board, or (b) with respect to any other Participant, a committee consisting of individuals then serving as the Chief Executive Officer of the Company, the Chief Financial Officer of the Company, and the Head of Human Resources of the Company.
- 12.2 **“Affiliate”** means, with respect to the Company, any other person that directly or indirectly controls, is under common control with, or is controlled by, the Company. As used herein the term “control” means the possession by a person, directly or indirectly, of the power to direct or cause the direction of the management and policies of another person, whether through ownership of 50% or more of the voting security of such other person, by contract, or otherwise.
- 12.3 **“Beneficiary”** means the beneficiary designated by the Participant under the Company’s group life insurance plan, or such other beneficiary as designated in writing by the Participant in the form as determined by the Administrator.
- 12.4 **“Cause”** means the occurrence of any of the following:
- (a) the Participant’s commission of an act of dishonesty that results, or is intended to result, in material gain or personal enrichment of the Participant or that has, or is intended to have, a material detrimental effect on the reputation or business of the Company or the Parent;
  - (b) the Participant’s commission of an act or acts of fraud, gross negligence, or a crime constituting a felony (other than relating to the operation of a motor vehicle), or the Participant’s conviction of, the indictment for (or its procedural equivalent), or the entering of a guilty plea or plea of no contest with respect to, a felony, the equivalent thereof, or any other crime with respect to which imprisonment of one year or more is a possible punishment;
  - (c) any material breach by the Participant of any restrictive, non-compete, or similar covenants described in this Plan or in any employment agreement or other written agreement or policy relating to the Participant’s service with the Company or the Parent;
  - (d) the Participant’s repeated refusal or failure to perform specific directives of the Company, the Parent, or any officer or employee to whom the Participant reports to the extent that such directives are consistent with the scope and nature of the Participant’s duties and responsibilities as an employee or service provider of the Company or the Parent, including the Participant’s insubordination and/or material breach of the Company’s or the Parent’s ethics or business conduct policy.

The determination of Cause shall be made by the Administrator, in its sole discretion.

**12.5 “Change in Control”** means the occurrence of any of the following, as determined by the Administrator:

- (a) the acquisition by any Person, in one or a series of related transactions, of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 50% or more of the combined voting power of the Company or the Parent’s equity; excluding, however, the following: (i) any acquisition by the Company; (ii) any acquisition by a lender to the Company pursuant to a debt restructuring thereof; (iii) any acquisition by, or consummation of a Corporate Transaction with an Affiliate; or (iv) a Non-Control Transaction; or
- (b) a Corporate Transaction unless such Corporate Transaction is a Non-Control Transaction.

Notwithstanding the foregoing, an event or occurrence described above will not constitute a Change in Control, unless the event or occurrence also qualifies as a “change in control event” within the meaning of Code Section 409A.

**12.6 “Change in Control Date”** means the date after the Effective Date that a Change in Control first occurs. For the avoidance of doubt, a Change in Control will occur upon its final closing, as determined by the Administrator.

**12.7 “Change in Control Health Benefit”** is a cash payment to a Terminated Participant sufficient on an after tax basis to pay, in the good-faith estimate of the Company determined as of the Termination Date, 100% of the cost of health benefit coverage continuation for the Terminated Participant and his or her eligible dependents for a period of six (6) months following the Termination Date; provided that to the extent that the payment of or promise to pay the Change in Control Health Benefit would result in adverse tax or other consequences to the Company or the Parent under Section 4980D of the Code, or other Code section, ERISA, or applicable law, the Company and the Participant will enter into an alternative arrangement providing for the Change in Control Health Benefit (or an economic equivalent thereto) which does not cause the imposition of taxes or adverse consequences; provided, further, that, if the Company’s accountants reasonably determine that no alternative arrangement is feasible, then the Participant will forfeit the right to the Change in Control Health Benefit without consideration therefor.

**12.8 “Change in Control Protection Period”** is the period commencing on the thirtieth (30th) day immediately preceding a Change in Control Date and ending on the three (3) month anniversary of the Change in Control Date.

**12.9 “Code”** means the Internal Revenue Code of 1986, as amended from time to time.

- 12.10** “**Company**” means Harmony Biosciences, LLC, a Delaware limited liability company, including any successor entity or any successor to the assets of the Company that has assumed the Plan.
- 12.11** “**Comparable Position**” means a position that would (a) provide the Participant with base compensation and benefits that are comparable in the aggregate to those provided to the Participant prior to the Change in Control Date; (b) provide the Participant with a bonus opportunity that is comparable to the opportunity provided to the Participant prior to the Change in Control Date; (c) be in a location that would not require the Participant to increase his/her daily one way commuting distance by more than fifty (50) miles as compared to the Participant’s commuting distance immediately prior to the Change in Control Date; and (d) have job skill requirements and duties that are comparable to the requirements and duties of the position held by the Participant prior to the Change in Control Date. The Company has the sole discretion to determine if a position is a “Comparable Position” and such determination shall be final, conclusive and binding and no one factor is determinative of whether a position is a Comparable Position.
- 12.12** “**Competitive Activity**” means the Participant, anywhere in the world, directly or indirectly owning, managing, controlling, participating in, consulting with, rendering services for, or in any manner engaging in (i) any business that owns, licenses, markets, sells or distributes pharmaceutical product(s) or biologic product(s) that directly compete with (i.e., have substantially the same approved indications in such portion of the world) pharmaceutical product(s) or biologic product(s) owned, licensed, marketed, sold or distributed by the Parent or the Company as of the Termination Date for any reason of the Participant’s service with the Parent or the Company in such portion of the world or (ii) any business with whom the Parent or the Company has entertained discussions, or has requested and received information, relating to the acquisition of such business by the Parent or the Company within twelve (12) months prior to the Termination Date of termination for any reason of the Participant’s service with the Company or the Parent; *provided, however*, that nothing herein shall prohibit the Participant from being a passive owner of not more than 5% of the outstanding stock of any class of any entity that is publicly traded, so long as the Participant has no active participation in the business of such entity.
- 12.13** “**Corporate Transaction**” means the consummation of a reorganization, merger or consolidation involving the Parent or the Company or sale or other disposition of all or substantially all of the assets of the Company, as determined by the Administrator.
- 12.14** “**Disability**” means a disability as determined in accordance with the Company’s (or the Parent’s) long-term disability plan or program in effect on the date that the disability first occurs.
- 12.15** “**Effective Date**” means June [\*], 2020.
- 12.16** “**Employee**” means a regular full-time employee of the Company or the Parent. The term “Employee” excludes (i) individuals who are classified, in the Company’s or Parent’s sole



discretion, as seasonal employees, leased employees, independent contractors, temporary employees, per diem employees, consultants, or special project employees (including interns and co-op employees); (ii) individuals who are engaged under an agreement which provides that the individual is not eligible to participate in the Plan; or (iii) individuals who are employed pursuant to an employment agreement or offer letter that provides for the payment of severance upon a termination of employment with the Company or the Parent.

The determination of who is an Employee for purposes of this Plan shall be made by the Administrator in its sole discretion, and any individual who is excluded from being considered an Employee by the Administrator shall be excluded from the definition of Employee regardless of the individual's reclassification by (1) the Internal Revenue Service for tax withholding purposes, or (2) by any other federal, state, or local administrative agency, tribunal, or court.

**12.17** "ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time and any successor statute thereto, and the rules and regulations promulgated thereunder.

**12.18** "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time and any successor statute thereto, and the rules and regulations promulgated thereunder.

**12.19** "Good Reason" means any of the following actions, taken without the consent of the Participant:

- (a) a material diminution in the Participant's base compensation, unless such diminution is part of broad-based reduction in pay across the Company;
- (b) a material diminution in the Participant's authority, duties, or responsibilities;
- (c) a material diminution in the authority, duties, or responsibilities of the individual to whom the Participant is required to report, including a requirement that the Participant report to a corporate officer or employee instead of reporting directly to the Parent Board;
- (d) a material diminution in the budget over which the Participant retains authority;
- (e) a material change in the geographic location at which the Participant must perform services; or
- (f) any material breach by the Company or Parent of this Plan or the Participant's employment agreement.

A Termination shall not be considered a Termination for Good Reason giving the Participant a right to Severance Benefits under Section 3, unless (a) the Participant notifies the Company or Parent of the event constituting Good Reason within thirty (30) days of having actual knowledge of such event, (b) the Company or the Parent has been given at

least thirty (30) days to cure the event purporting to constitute Good Reason (the “Cure Period”), and (c) if the Company or Parent fails to cure such event, the Participant terminates employment within sixty (60) days of the expiration of the Cure Period. If the event purporting to constitute Good Reason is cured during the Cure Period, such event shall not constitute Good Reason.

- 12.20** “**Key Executives**” are the individuals then serving as the Chief Executive Officer of the Company, the Chief Financial Officer of the Company, and the Head of Human Resources of the Company
- 12.22** “**Non-Control Transaction**” means a Corporate Transaction as a result of which the combined voting power of the outstanding units of the Parent or the Company immediately prior to such Corporate Transaction will entitle the holders thereof immediately prior to such Corporation Transaction to exercise, directly or indirectly, more than 50% of the combined voting power of all units, or if applicable, the shares of capital stock, entitled to vote generally in the election of directors or similar governing body of the entity resulting from such Corporate Transaction immediately after such Corporate Transaction (including, without limitation, a corporation which as a result of such transaction owns the Company or all or substantially all of the Company’s assets).
- 12.23** “**Parent**” shall mean Harmony Biosciences Holdings, Inc., a Delaware corporation.
- 12.24** “**Parent Board**” shall mean the Parent’s board of managers or similar governing body as in effect from time to time.
- 12.25** “**Participant**” shall mean an Employee who has been designated to participate in the Plan in accordance with Section 2 and who is participating in the Plan on his or her Termination Date. Following a Participant’s death, references to Participant with respect to such decedent shall mean such Participant’s Beneficiary.
- 12.26** “**Person**” shall mean 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.
- 12.27** “**Plan**” means this Harmony Biosciences, LLC Separation Plan.
- 12.28** “**Plan Year**” means each calendar year, with a short plan year from June [\*], 2020, through December 31, 2020.
- 12.29** “**Salary**” means the highest annual base salary paid to the Participant during the 12-month period immediately preceding the earlier of (i) such Participant’s Termination Date or (ii) the Change in Control Date, with such amount increased (if applicable) to take into account any elective or mandatory deferrals.

12.30 “**Severance Benefits**” are the compensation and benefits payable or provided to a Terminated Participant under Section 3.

12.31 “**Terminated Participant**” means a Participant who has incurred a Termination.

12.32 “**Termination**” shall mean the termination of a Participant’s employment with the Company or the Parent by the Company (or Parent) without Cause (other than due to death or Disability) or by the Participant for Good Reason.

12.33 “**Termination Date**” means the date of a Termination of a Participant.

IN WITNESS WHEREOF, the Company has caused this indenture to be executed, effective as of the date set forth above.

**HARMONY BIOSCIENCES, LLC**

By: \_\_\_\_\_

Title: \_\_\_\_\_

**ATTEST:**

By: \_\_\_\_\_

Title: \_\_\_\_\_

**EXHIBIT A**  
**RELEASE**

This Release (the "Release") is dated as of this \_\_\_ day of \_\_\_\_\_, 20\_\_\_, by and between Harmony Biosciences, LLC (hereinafter, sometimes individually referred to as "Harmony" and collectively, together with the Parent, referred to as the "Company.")) and \_\_\_\_\_ (the "Employee", together with the Company, the "Parties"). Capitalized terms not herein defined shall have the meanings ascribed them in the Plan.

WHEREAS, the Employee is a participant in the Harmony Biosciences, LLC Separation Plan, as may be amended (the "Plan");

WHEREAS, the Employee's service with the Company has been terminated effective \_\_\_\_\_; and

WHEREAS, pursuant to the Plan, the Employee is entitled to certain compensation and benefits upon such termination, contingent upon the execution of this Release.

NOW, THEREFORE, in consideration of the premises and mutual agreements contained herein and in the Plan, Harmony and the Employee agree as follows:

1. **Termination of Employment.** The Employee acknowledges that the Employee's Termination Date is \_\_\_\_\_.

2. **Full Release by Employee.** For the consideration expressly set forth in the Plan,<sup>1</sup> the Employee, for himself, the Employee's heirs, executors, administrators, successors and assigns (hereinafter collectively referred to as the "Releasers"), hereby irrevocably, unconditionally and fully releases, acquits, and discharges the Company, its parents, subsidiaries, affiliates, insurers, predecessors, successors, and assigns, and their respective predecessors, parents, affiliates, subsidiaries, divisions, equity holders, members, managers, partners, officers, directors, officers, employees, legal advisors, representatives, trustees, benefits plans, lenders, investors and agents (all such persons, firms, corporations and entities being deemed beneficiaries hereof and are referred to herein as the "Company Entities") from any and all actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, bonuses, controversies, agreements, liabilities, promises, claims, obligations, costs, losses, damages and demands of whatsoever character, in law or in equity, whether or not known, suspected or claimed, which the Releasers ever had, have, or may have from the beginning of time through the Termination Date, or if later, the date of this Release, against the Company Entities arising out of or in any way related to Employee's employment or service or termination of the Employee's employment or service, including, without limitation, claims arising under the Americans With Disabilities Act, the Age Discrimination in Employment Act (as amended by the Older Workers Benefit Protection Act), the National Labor Relations Act, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974, the Equal Pay Act, the Fair Credit Reporting Act, the Genetic Information and Discrimination Act, Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Acts of 1866, 1871 and 1991, including Section 1981-1988

<sup>1</sup> Amend as applicable at time of termination to reflect other agreements.

of the Civil Rights Act, the Labor Management Relations Act, the Vietnam Era Veterans Readjustment Act of 1974, the Rehabilitation Act of 1973, the Worker Adjustment and Retraining Notification Act, Section 806 of the Corporate and Criminal Fraud Accountability Act of 2002, the Immigration Reform Control Act, the Occupational Safety and Health Act, the Family and Medical Leave Act, [INSERT STATE/LOCAL LAW],<sup>2</sup> each as may be amended, and/or any other federal, state or local human rights, civil rights, wage-hour, pension or labor law, rule, statute, regulation, constitution or ordinance and/or public policy, contract or tort law, or any claim of retaliation under such laws, or any claim of breach of any contract (whether express, oral, written or implied from any source), or any claim of intentional or negligent infliction of emotional distress, tortious interference with contractual relations, wrongful or abusive discharge, defamation, prima facie tort, fraud, negligence, loss of consortium, or any action similar thereto against the Company Entities, including any claim for attorneys' fees; [provided, however, that the Releasors do not waive any rights or release the Company Entities from the Severance Benefits, COBRA continuation coverage rights that are available under applicable law (at the Employee's sole cost), indemnification and/or contribution or directors' and officers' insurance rights the Employee may have in respect of Employee's service with the Company, and vested benefits, if any, to of Employee under the terms any employee benefit plan; and further provided, that the Releasors do not release any right to challenge, under the Older Worker's Benefit Protection Act, the knowing and voluntary nature of the release of any age claims in this Release, in court or before the Equal Employment Opportunity Commission ("EEOC") or any right to file an administrative charge with the EEOC or any other similar federal, state, or local agency (provided, that any right to recover monetary damages or other personal relief in any proceeding shall be released and waived), or any claims that cannot be waived by law.]<sup>3</sup>

By executing this Release, the Employee acknowledges that:

(a) This Release does not include claims arising after the date of execution by the Employee below;

(b) The Employee acknowledges that the Employee has had **twenty-one (21)/forty-five (45)** days to consider this Release's terms (commencing from delivery of the Agreement). Employee may accept this Release by signing it and returning it to General Counsel, Harmony Biosciences, LLC, 630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA 19462.

(c) [The Employee understands that on the eighth (8th) day after the date of execution of this Release, this Release becomes effective and, as of that date, the Employee may not change the Employee's decision or seek any other remuneration in any form; provided, however, that the Employee has a seven (7) day revocation period (beginning on the date of execution) that expires at 5:00 pm on such seventh (7th) day. If the Employee intends to revoke this Release the Employee must advise the [General Counsel of the Company] on or before the expiration of this seven (7) day revocation period by delivering to General Counsel, Harmony Biosciences, LLC, 630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, written notification of the Employee's intention to revoke this Release, which written notification makes specific reference to this Release.]<sup>4</sup>

<sup>2</sup> Applicable laws subject to revision.

<sup>3</sup> Note to client: To be discussed.

<sup>4</sup> Amend as applicable at time of termination.

(d) The Employee by signing this Release acknowledges that the Employee has had a full and fair opportunity to review, consider, and negotiate the terms of this Release, that the Employee has been advised to seek and has sought the advice of an independent attorney of the Employee's choosing in connection with the Employee's decision whether to accept the benefits that have been offered to the Employee under this Release, and has reviewed this Release with advisors of the Employee's choice, that the Employee has read and understands this Release, and that the Employee has signed this Release freely and voluntarily, without duress, coercion or undue influence and with full and free understanding of its terms.

(e) The Release is not intended, and shall not be construed, as an admission that any of the Parties has violated any federal, state, or local law (statutory or decisional), ordinance or regulation, breached any contract or committed any wrong whatsoever. Should any provision of this Release require interpretation or construction, it is agreed by the Parties that the entity interpreting or construing this release shall not apply a presumption against one Party by reason of the rule of construction that a document is to be construed more strictly against the Party who prepared the document.

(f) For the purpose of implementing a full, knowing, and complete release and discharge of the Company Entities, the Employee expressly acknowledges that this Release is intended to include in its effect, without limitation, all claims which the Employee does not know or suspects to exist in the Employee's favor at the time of execution hereof, and that this Release contemplates the extinguishment of any such claim or claims.

(g) The Employee further acknowledges and agrees that in the event any charge, complaint, action, or proceeding was or is filed on behalf of the Employee in any agency, court, or other forum against the Company Entities based on any conduct from the beginning of the world up to and including the date of this Release, no Releasor will accept any award, recovery, settlement or relief there from.

(h) The Employee represents that neither the Employee nor any person acting on the Employee's behalf has filed or caused to be filed any lawsuit, complaint, or charge against any of the Company Entities in any court, any municipal, state or federal agency, or any other tribunal. The Employee agrees that the Employee will not, to the fullest extent permitted by law, sue or file a charge, complaint, grievance or demand for arbitration in any forum pursuing any claim released under this Release or assist or otherwise participate in any claim, arbitration, suit, action, investigation or other proceeding of any claim released hereunder.

(i) The Employee represents and warrants that the Employee has not assigned or conveyed to any other person or entity any part of or interest in any of the claims released in this Release. The Employee further expressly waives any claim to any monetary or other damages or any other form of recovery in connection with any claim released in this release or any proceeding that violates this Release.

(j) Employee affirms that the Employee has not suffered any known workplace injuries or occupational diseases and that the Employee has not been retaliated against for reporting any allegations of wrongdoing by the Company or its affiliates, or their respective officers or board members, including any allegations of corporate fraud.

3. **Miscellaneous.**

(a) This Release shall be governed in all respects by the laws of the State of Pennsylvania without regard to the principles of conflict of law.

(b) In the event that any one or more of the provisions of this Release is held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions will not in any way be affected or impaired thereby. Moreover, if any one or more of the provisions contained in this Release is held to be excessively broad as to duration, scope, activity or subject, such provisions will be construed by limiting and reducing them so as to be enforceable to the maximum extent compatible with applicable law.

(c) This Release may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(d) The headings used in this Release are included solely for convenience and shall not affect or be used in connection with the interpretation of this Release. Wherever the context so requires, the masculine gender includes the feminine or neuter, and the singular number includes the plural and conversely.

(e) This Release (together with the Plan)<sup>5</sup> represents the entire agreement between the Parties with respect to the subject matter hereof and may not be amended except in a writing signed by the Company and the Employee. If any dispute should arise under this Release, it shall be settled in accordance with the terms of the Plan.

(f) This Release shall be binding on the executors, heirs, administrators, successors, and assigns of the Employee and the successors and assigns of Company and shall inure to the benefit of the respective executors, heirs, administrators, successors, and assigns of the Company Entities and the Releasors.

---

<sup>5</sup> Amend as applicable for any other arrangement (e.g., employment agreement).

**BY SIGNING BELOW, THE EMPLOYEE REPRESENTS AND WARRANTS THAT THE EMPLOYEE HAS CAREFULLY READ AND FULLY UNDERSTANDS THE PROVISIONS OF THIS RELEASE AND THE EMPLOYEE HAS HAD AN OPPORTUNITY TO CONSULT WITH LEGAL COUNSEL. THE EMPLOYEE SIGNS THE EMPLOYEE'S NAME VOLUNTARILY AND WITH A FULL UNDERSTANDING OF ITS LEGAL CONSEQUENCES. THE EMPLOYEE HEREBY ACCEPTS AND AGREES TO ALL OF THE TERMS OF THIS RELEASE KNOWINGLY AND VOLUNTARILY.**

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of \_\_\_\_\_.

**HARMONY BIOSCIENCES, LLC**

By: \_\_\_\_\_

Name:

Title:

**EMPLOYEE**

\_\_\_\_\_



*The accompanying financial statements give effect to a 1-for-8.215 reverse stock split of the common stock of Harmony Biosciences Holdings, Inc. which will take place prior to the effective date of the registration statement. The following report is in the form which will be furnished by Deloitte & Touche LLP, an independent registered public accounting firm, upon completion of the 1-for-8.215 reverse stock split of the common stock of Harmony Biosciences Holdings, Inc. described in Note 17 to the financial statements and, assuming that from April 10, 2020 to the date of such completion, no other material events have occurred that would affect the accompanying financial statements or disclosures therein.*

/s/ Deloitte & Touche LLP

Chicago, Illinois  
August 11, 2020

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the use in this Registration Statement No. 333-240122 on Form S-1 of our report dated April 10, 2020 (August , 2020 as to the effects of the reverse stock split discussed in Note 17), relating to the financial statements of Harmony Biosciences Holdings, Inc. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

Chicago, Illinois  
August , 2020