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

FORM 10-Q

(Mark One)
☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended September 30, 2022
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number: 001-39450

HARMONY BIOSCIENCES HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-2279923**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA	**19462**
(Address of principal executive offices)	(Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 value per share	HRMY	The Nasdaq Stock Market LLC (Nasdaq Global Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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, 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 28, 2022, there were 59,317,554 shares of the registrant's common stock, par value $0.00001 value per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 261,343	$ 234,309
Investments, short-term	46,420	—
Trade receivables, net	55,065	34,843
Inventory, net	3,900	4,432
Prepaid expenses	11,246	7,637
Other current assets	4,108	3,218
Total current assets	382,082	284,439
NONCURRENT ASSETS:		
Property and equipment, net	680	820
Restricted cash	750	750
Investments, long-term	8,280	—
Intangible assets, net	166,914	143,919
Deferred tax asset	81,679	—
Other noncurrent assets	3,079	3,515
Total noncurrent assets	261,382	149,004
TOTAL ASSETS	$ 643,464	$ 433,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 10,049	$ 1,001
Accrued compensation	8,331	9,165
Accrued expenses	85,606	40,249
Current portion of long-term debt	2,000	2,000
Other current liabilities	1,371	1,360
Total current liabilities	107,357	53,775
NONCURRENT LIABILITIES:		
Long-term debt, net	189,725	189,984
Other noncurrent liabilities	2,498	3,177
Total noncurrent liabilities	192,223	193,161
TOTAL LIABILITIES	299,580	246,936
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2022 and December 31, 2021, respectively; 59,304,408 shares and 58,825,769 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid in capital	664,700	640,104
Accumulated other comprehensive income (loss)	(178)	—
Accumulated deficit	(320,639)	(453,598)
TOTAL STOCKHOLDERS' EQUITY	343,884	186,507
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 643,464	$ 433,443

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 INCOME
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net product revenues	$ 117,206	$ 80,732	$ 309,547	$ 214,227
Cost of product sold	22,959	14,604	56,596	37,701
Gross profit	94,247	66,128	252,951	176,526
Operating expenses:				
Research and development	40,548	11,739	60,794	22,916
Sales and marketing	20,467	16,480	58,210	49,009
General and administrative	21,331	16,856	61,374	45,704
Total operating expenses	82,346	45,075	180,378	117,629
Operating income	11,901	21,053	72,573	58,897
Loss on debt extinguishment	—	(26,146)	—	(26,146)
Other expense (income), net	56	—	96	(15)
Interest expense, net	(3,990)	(5,429)	(12,086)	(19,783)
Income (loss) before income taxes	7,967	(10,522)	60,583	12,953
Income tax benefit (expense)	79,976	902	72,376	(1,070)
Net income	$ 87,943	$ (9,620)	$ 132,959	$ 11,883
Unrealized loss on investments	(149)	—	(178)	—
Comprehensive income	$ 87,794	$ (9,620)	$ 132,781	$ 11,883
EARNINGS PER SHARE:				
Basic	$ 1.48	$ (0.17)	$ 2.25	$ 0.21
Diluted	$ 1.44	$ (0.17)	$ 2.18	$ 0.20
Weighted average number of shares of common stock - basic	59,234,720	57,722,163	59,070,063	57,188,101
Weighted average number of shares of common stock - diluted	61,207,625	57,722,163	60,921,482	58,776,158

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 STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance as of December 31, 2021	58,825,769	$ 1	$ 640,104	$ —	$ (453,598)	$ 186,507
Net income	—	—	—	—	132,959	132,959
Unrealized loss on investments	—	—	—	(178)	—	(178)
Issuance of common stock	8,050	—	408	—	—	408
Exercise of options	470,589	—	5,275	—	—	5,275
Stock-based compensation	—	—	18,913	—	—	18,913
Balance as of September 30, 2022	59,304,408	$ 1	$ 664,700	$ (178)	$ (320,639)	$ 343,884

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance as of June 30, 2022	59,117,749	$ 1	$ 655,143	$ (29)	$ (408,582)	$ 246,533
Net income	—	—	—	—	87,943	87,943
Unrealized loss on investments	—	—	—	(149)	—	(149)
Issuance of common stock	8,050	—	408	—	—	408
Exercise of options	178,609	—	2,143	—	—	2,143
Stock-based compensation	—	—	7,006	—	—	7,006
Balance as of September 30, 2022	59,304,408	$ 1	$ 664,700	$ (178)	$ (320,639)	$ 343,884

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance as of December 31, 2020	56,890,569	$ 1	$ 585,374	$ (488,195)	$ 97,180
Net income	—	—	—	11,883	11,883
Issuance of common stock	1,270,462	—	29,700	—	29,700
Exercise of stock options	253,515	—	1,794	—	1,794
Stock-based compensation	—	—	11,461	—	11,461
Balance as of September 30, 2021	58,414,546	$ 1	$ 628,329	$ (476,312)	$ 152,018

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance as of June 30, 2021	57,000,139	$ 1	$ 593,242	$ (466,692)	$ 126,551
Net income	—	—	—	(9,620)	(9,620)
Issuance of common stock	1,270,462	—	29,700	—	29,700
Exercise of options	143,945	—	1,134	—	1,134
Stock-based compensation	—	—	4,253	—	4,253
Balance as of September 30, 2021	58,414,546	$ 1	$ 628,329	$ (476,312)	$ 152,018

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)

	Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 132,959	$ 11,883
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	312	299
Intangible amortization	17,005	13,781
Stock-based and employee stock purchase compensation expense	18,913	11,461
Stock appreciation rights market adjustment	321	261
Debt issuance costs amortization	1,241	1,820
Deferred taxes	(81,679)	—
Investment securities interest income	(225)	—
Loss on debt extinguishment	—	26,146
Other non-cash expenses	1,042	916
Change in operating assets and liabilities:		
Trade receivables	(20,222)	(11,030)
Inventory	532	(982)
Prepaid expenses and other assets	(4,479)	(3,715)
Trade payables	9,048	1,623
Accrued expenses and other current liabilities	43,171	8,545
Other non-current liabilities	(151)	16
Net cash provided by operating activities	117,788	61,024
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investment securities	(55,637)	—
Proceeds from maturities and sales of investment securities	872	—
Purchase of property and equipment	(172)	(298)
Milestone payments	(40,000)	(100,000)
Net cash used in investing activities	(94,937)	(100,298)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	408	30,000
Common stock issuance costs	—	(300)
Proceeds from long term debt	—	200,000
Debt issuance costs	—	(9,147)
Extinguishment of debt	—	(200,000)
Extinguishment of debt exit fees	—	(22,000)
Principal repayment of long term debt	(1,500)	—
Proceeds from exercised options	5,275	1,794
Net cash provided by financing activities	4,183	347
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	27,034	(38,927)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	235,059	229,381
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 262,093	$ 190,454
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 11,334	$ 15,997

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

The Company

Harmony Biosciences Holdings, Inc., and its consolidated subsidiary (the "Company") was founded in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company. The Company converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017 and, in February 2020, the Company changed its name to Harmony Biosciences Holdings, Inc. The Company's operations are conducted in its wholly owned subsidiary, Harmony Biosciences, LLC ("Harmony"), which was formed in May 2017. The Company is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

Initial Public Offering

In August 2020, the Company completed its initial public offering ("IPO") of common stock, in which it sold 6,151,162 shares, including 802,325 shares pursuant to the underwriters' over-allotment option. The shares were sold at a price of $24.00 per share for net proceeds of approximately $135,435, after deducting underwriting discounts and commissions and offering expenses of approximately $12,193 payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's convertible preferred stock were automatically converted into shares of common stock and the accrued dividend payable to holders of the convertible preferred stock was paid out in shares of common stock, resulting in a total of 42,926,630 shares of common stock being issued to former holders of the Company's convertible preferred stock. Warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for a total of 410,239 shares of common stock.

2. LIQUIDITY AND CAPITAL RESOURCES

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 had an accumulated deficit of $320,639 and $453,598, as of September 30, 2022 and December 31, 2021, respectively. As of September 30, 2022, the Company had cash, cash equivalents and investments of $316,043.

The Company believes that its existing cash and cash equivalents on hand as of September 30, 2022, as well as additional cash generated from operating and financing activities will meet its operational liquidity needs and fund its planned investing activities for the next twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

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 unaudited condensed consolidated balance sheet as of September 30, 2022, the unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2022, and 2021, and the unaudited condensed

consolidated statements of operations and comprehensive income and the unaudited condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 2022 and 2021, are unaudited. The balance sheet as of September 30, 2022, was derived from audited financial statements as of and for the year ended December 31, 2021. 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, 2021, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2022, and the results of its operations and its cash flows for the nine months ended September 30, 2022 and 2021. The unaudited condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

The Company has updated certain prior period disclosures within Note 11 in order to conform with current period presentation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosures in the unaudited condensed consolidated financial statements, including the notes thereto, and elsewhere in this report. Actual results may differ significantly from estimates, which include rebates due pursuant to commercial and government contracts, accrued research and development expenses, stock-based compensation expense and income taxes.

Uncertainties related to the magnitude and duration of COVID-19, the extent to which it will impact our future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending and health insurance coverage, the speed of the anticipated recovery and governmental and business reactions to the pandemic have increased the complexity of developing estimates and assumptions used in the preparation of the unaudited condensed consolidated financial statements, including the carrying amounts of long-lived assets, and the intangible asset. Actual results may differ significantly from our estimates as a result of COVID-19.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents and restricted cash 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 and debt securities that approximate fair value. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that equal the amount reflected in the statements of cash flows.

	As of	
	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 261,343	$ 234,309
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 262,093	$ 235,059

Restricted cash includes amounts required to be held as a security deposit in the form of letters of credit for the Company's credit card program and the fleet program.

Investments

The Company's investments consist of debt securities that are classified as available-for-sale. The short-term and long-term investments are carried at fair value and unrealized gains and losses are recorded as a component of accumulated comprehensive income in stockholders' equity. The amortization of premiums and accretion of discounts adjust the carrying value of investments and are recorded in interest expense, net, on the unaudited condensed consolidated statements of operations and comprehensive income. Interest income and realized gains and losses, if any, are also recorded in interest expense, net, on the unaudited condensed consolidated statement of operations and comprehensive income. Realized gains and losses that result from the sale of investments are determined on a specific identification basis.

At each reporting period, the Company reviews any unrealized losses position to determine if the decline in the fair value of the underlying investments is a result of credit losses or other factors. If the assessment indicates that a credit loss exists, any impairment is recognized as an allowance for credit losses in our consolidated statement of operations.

Concentrations of Risk

Substantially all of the Company's cash and money market funds are held in two financial institutions. Due to their size, the Company believes these financial institutions represent minimal credit risk. Deposits 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.

The Company is also subject to credit risk from its trade receivables related to its product sales. The Company extends credit to specialty pharmaceutical distribution companies within the United States. Customer creditworthiness is monitored and collateral is not required. Historically, the Company has not experienced credit losses on its accounts receivable. The Company monitors its exposure within accounts receivable and would record a reserve against uncollectible accounts receivable if necessary As of September 30, 2022, three customers accounted for 100% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 47% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 30% of gross accounts receivable; and, PANTHERx Specialty Pharmacy LLC ("Pantherx", which accounted for 23% of gross accounts receivable. As of December 31, 2021, three customers accounted for 100% of gross accounts receivable; Accredo, which accounted for 40% of gross accounts receivable; Pantherx, which accounted for 31% of gross accounts receivable; and CVS Caremark, which accounted for 29% of gross accounts receivable.

For the nine months ended September 30, 2022, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 40% of gross product revenues; Pantherx accounted for 30% of gross product revenues; and Accredo accounted for 30% of gross product revenues. For the nine months ended September 30, 2021, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 36% of gross product revenues; Pantherx accounted for 36% of gross product revenues; and Accredo accounted for 28% of gross product revenues.

The Company depends on a single source supplier for each of its product and active pharmaceutical ingredient.

Recently Issued Accounting Pronouncements

ASU 2020-04, Reference Rate Reform (Topic 848). In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*, which provides guidance related to reference rate reform. The pronouncement provides temporary optional expedients and exceptions to the current guidance on contract modifications and hedge accounting to ease the financial reporting burden related to the expected market

transition from the London Interbank Offered Rate ("LIBOR") and other interbank offered rates to alternative reference rates. The guidance was effective upon issuance and generally can be applied to applicable contract modifications through December 31, 2022. The Company is currently evaluating the impact of the transition from LIBOR to alternative reference rates but does not expect a significant impact to its condensed consolidated financial statements.

4. INVESTMENTS

The carrying value and amortized cost of the Company's available-for-sale debt securities, summarized by type of security, consisted of the following:

	September 30, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	$ 12,089	1	(35)	$ 12,055
Corporate debt securities	30,077	4	(80)	30,001
U.S. government securities	4,382	—	(18)	4,364
Total short-term investments	$ 46,548	5	(133)	$ 46,420
Long-term:				
Corporate debt securities	$ 8,074	3	(50)	$ 8,027
U.S. government securities	256	—	(3)	253
Total long-term investments	$ 8,330	3	(53)	$ 8,280

The Company classifies investments with an original maturity of less than one year as current and investments with an original maturity date of greater than one year as noncurrent on its unaudited condensed consolidated balance sheet. The investments classified as noncurrent have maturity dates ranging from 1-2 years.

5. FAIR VALUE MEASUREMENTS

The Company's unaudited condensed consolidated financial statements include cash, cash equivalents, restricted cash, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value.

It is the Company's policy to measure non-financial assets and liabilities at fair value on a nonrecurring basis. These non-financial assets and liabilities 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 based on the fair value hierarchy that prioritizes inputs to valuation techniques used to measure fair value 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.

Money market funds are classified as Level 1 fair value instruments. Investments in available-for-sale debt securities are classified as Level 2 and carried at fair value, which we estimate utilizing a third-party pricing service. The pricing service utilizes industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. We validate valuations obtained from third-party services by obtaining market values from other pricing sources. The Company did not classify any assets or liabilities as Level 3 as of September 30, 2022 or December 31, 2021.

The Company's assets measured at fair value consisted of the following:

	September 30, 2022			December 31, 2021		
	Total	Level 1	Level 2	Total	Level 1	Level 2
Assets						
Cash equivalents	$ 180,513	180,513	—	$ 156,782	156,782	—
Commercial paper	12,055	—	12,055	—	—	—
Corporate debt securities	38,028	—	38,028	—	—	—
U.S. government securities	4,617	—	4,617	—	—	—
Total	$ 235,213	180,513	54,700	$ 156,782	156,782	—

6. INVENTORY

Inventory, net consisted of the following:

	As of	
	September 30, 2022	December 31, 2021
Raw materials	$ 605	$ 986
Work in process	1,802	1,787
Finished goods	2,137	2,108
Inventory, gross	4,544	4,881
Reserve for excess inventory	(644)	(449)
Total inventory, net	$ 3,900	$ 4,432

7. INTANGIBLE ASSETS

In August 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 under the provisions of the 2017 LCA (defined below) which the Company capitalized as an intangible asset. The Company determined a useful life of 10 years for such intangible asset, and, as of September 30, 2022, the remaining useful life was 7.0 years.

In October 2020, the Company received FDA approval for the New Drug Application ("NDA") for WAKIX for the treatment of cataplexy in adult patients with narcolepsy. This event triggered a milestone payment of $100,000 under the provisions of the 2017 LCA which the Company capitalized as an intangible asset and paid in January of 2021. The Company determined a useful life of 9 years for such intangible asset, and, as of September 30, 2022, the remaining useful life was 7.0 years.

In February 2022, the Company attained $500,000 in life-to-date aggregate net sales of WAKIX in the United States. This event triggered a final $40,000 payment under the provisions of the 2017 LCA which the

Company capitalized as an intangible asset and paid in March of 2022. The Company determined a useful life of 7.6 years for such intangible asset, and, as of September 30, 2022, the remaining useful life was 7.0 years.

Amortization expense was $5,962 and $4,573 for the three months ended September 30, 2022 and 2021, respectively, and $17,005 and $13,781 for the nine months ended September 30, 2022 and 2021, respectively, and is recorded in general and administrative expenses on the unaudited condensed consolidated statements of operations and comprehensive income.

Future amortization expense relating to unamortized intangible assets as of September 30, 2022 for the periods indicated below consists of the following:

Years ending December 31,	
2022 (Excluding the nine months ended September 30, 2022)	$ 5,961
2023	23,845
2024	23,845
2025	23,845
2026	23,845
Thereafter	65,573
Total	$ 166,914

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

	As of	
	September 30, 2022	**December 31, 2021**
Gross Carrying Amount	$ 215,000	$ 175,000
Accumulated Amortization	(48,086)	(31,081)
Net Book Value	$ 166,914	$ 143,919

8. LICENSE AND ASSET PURCHASE AGREEMENTS

In July 2017, Harmony entered into a License Agreement (“the 2017 LCA”) with Bioprojet Société 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. A milestone payment of $50,000 was due upon acceptance by the FDA of pitolisant’s NDA, which was achieved in February 2019 and was expensed within research and development for the year ended December 31, 2019. A milestone payment of $77,000, which included a $2,000 fee that is described below, was due upon FDA approval of WAKIX (pitolisant) for treatment of EDS in adult patients with narcolepsy, which was achieved in August 2019. The $2,000 payment and $75,000 milestone payment were paid in August and November 2019, respectively. In addition, a milestone payment of $102,000, which included a $2,000 fee was due upon the FDA approval of the NDA for WAKIX for the treatment of cataplexy in adult patients with narcolepsy. The $2,000 payment was paid in October 2020 and a $100,000 milestone payment was paid in January 2021. A final $40,000 milestone payment was paid to Bioprojet in March 2022 upon WAKIX attaining $500,000 in aggregate net sales in the United States. The 2017 LCA also requires a fixed trademark royalty and a tiered royalty based on net sales, which is payable to Bioprojet on a quarterly basis. The Company incurred $ 20,944 and $13,202 for the three months ended September 30, 2022 and 2021, respectively, and- $51,741 and $34,561 for the nine months ended September 30, 2022 and 2021, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of September 30, 2022 and December 31, 2021, the Company had accrued $20,944 and $16,396, respectively, for sales-based, trademark and tiered royalties.

On July 31, 2022, Harmony entered into a License and Commercialization Agreement (the “2022 LCA”) with Bioprojet whereby Harmony obtained exclusive rights to manufacture, use and commercialize one or more

new products based on pitolisant in the United States and Latin America, with the potential to add additional indications and formulations upon agreement of both parties. Harmony will pay an initial, non-refundable $30,000 licensing fee and additional payments of up to $155,000 are potentially due under the 2022 LCA upon the achievement of certain future development and sales-based milestones. In addition, there are certain payments due upon achievement of development milestones for new indications and formulations as agreed upon by both parties. The 2022 LCA also requires a fixed trademark royalty and a tiered royalty based on net sales upon commercialization, which will be payable to Bioprojet on a quarterly basis. Upon the closing of the 2022 LCA on September 28, 2022, the $30,000 licensing fee was recorded in research and development within the unaudited condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2022.

Agreement Related to Intellectual Property

In August 2021, the Company entered into an asset purchase agreement with ConSynance Therapeutics, Inc. (the "APA") to acquire HBS-102 (formerly referred to as "CSTI-100"), a potential first-in-class molecule with a novel mechanism of action. Under the terms of the APA, the Company acquired full development and commercialization rights globally, with the exception of Greater China, for $3,500. The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the assets acquired was concentrated in a single identified asset. Additionally, there are payments due under the APA upon the achievement of certain milestones including $1,750 for preclinical milestones, $19,000 for development milestones, $44,000 for regulatory milestones and $110,000 for sales milestones.

9. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	September 30, 2022	December 31, 2021
Royalties due to third parties	$ 20,944	$ 16,396
Rebates and other sales deductions	25,214	17,141
Interest	3,041	2,125
Selling and marketing	2,326	1,983
Research and development	1,852	658
Professional fees, consulting, and other services	1,229	1,645
Licensing fee	30,000	—
Other expenses	1,000	301
	$ 85,606	$ 40,249

10. DEBT

Blackstone Credit Agreement

In August 2021, the Company entered into the Blackstone Credit Agreement that provides for (i) a senior secured term loan facility in an aggregate original principal amount of $200,000 (the "Initial Term Loan") and (ii) a senior secured delayed draw term loan facility in an aggregate principal amount up to $100,000 (the "DDTL" and, together with the Initial Term Loan, the "Loans"). The DDTL was initially available to draw down through August 9, 2022. In August 2022, the Company entered into an agreement to extend the expiration date of the DDTL to August 9, 2023, for which the Company will pay a ticking fee at a rate of 1% per annum on the undrawn portion of the DDTL, which commenced on August 10, 2022.

The repayment schedule for the Initial Term Loan consists of quarterly $500 principal payments, which commenced on December 31, 2021, and increasing to quarterly $5,000 principal payments beginning on March 31, 2024, with a $145,500 payment due on the maturity date of August 9, 2026 ("Maturity Date"). Interest is

payable quarterly, which commenced on November 9, 2021, and continues through the Maturity Date. The Initial Term Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%.

Net cash received from the Initial Term Loan as a result of the transaction, less debt issuance costs of $8,151, was $191,849. The debt issuance costs related to the Initial Term Loan are being amortized as additional interest expense over the five-year loan term of the Blackstone Credit Agreement. In addition, the Company paid $1,000 in debt issuance costs relating the DDTL, which are recorded in other current assets within the unaudited condensed consolidated balance sheet. The fair value of the Initial Term Loan as of September 30, 2022 was $149,226.

Long-term debt, net consists of the following:

	September 30, 2022	December 31, 2021
Liability component - principal	$ 198,000	$ 199,500
Unamortized debt discount associated with debt financing costs	(6,275)	(7,516)
Liability component - net carrying value	191,725	191,984
Less current portion	(2,000)	(2,000)
Long-term debt, net	$ 189,725	$ 189,984

Future minimum payments relating to long-term debt, net as of September 30, 2022, for the periods indicated below consists of the following:

Years ending December 31,	
2022 (Excluding the nine months ended September 30, 2022)	$ 500
2023	2,000
2024	20,000
2025	20,000
2026	155,500
Thereafter	—
Total	$ 198,000

Interest expense related to the Company's long-term debt, net, is included in interest expense, net in the unaudited condensed consolidated statements of operations and comprehensive income and consists of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Interest on principal balance	$ 4,513	$ 5,030	$ 12,110	$ 18,122
Amortization of deferred financing costs	418	459	1,241	1,820
Total term loan interest expense	$ 4,931	$ 5,489	$ 13,351	$ 19,942

11. LEASES

In June 2018, the Company entered into an operating lease for approximately fifteen thousand square feet of office space in Plymouth Meeting, PA, which expires in May 2024. In December 2020, the Company entered into an operating lease for approximately thirteen thousand square feet of additional office space in Plymouth Meeting, PA, which expires in May 2024. The terms of the lease payments provide for rental payments on a monthly basis and on a graduated scale. The Company also leases a fleet of automobiles that are used by its sales representatives and are classified as operating leases.

Operating lease right-of-use assets and operating lease liabilities are recognized based on the present value of the future lease payments using our incremental borrowing rate. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Our leases have remaining lease terms of less than 1 year to 3 years, some of which may include the option to extend or terminate the leases.

The Company recorded operating lease costs of $378 and $359 for the three months ended September 30, 2022 and 2021, respectively, and $1,155 and $916 for the nine months ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, the weighted-average remaining lease term for operating leases was 1.9 years and the weighted-average discount rate for operating leases was 3.8%.

Supplemental balance sheet information related to operating leases was as follows:

Leases	Classification	September 30, 2022	December 31, 2021
Assets			
Operating lease right-of-use assets	Other noncurrent assets	$ 2,658	$ 3,298
Liabilities			
Operating lease liability, current portion	Other current liabilities	$ 1,598	$ 1,527
Operating lease liability, long-term	Other long-term liabilities	1,384	2,233
Total operating lease liabilities		$ 2,982	$ 3,760

Supplemental cash flow information related to operating leases was as follows:

	September 30, 2022	September 30, 2021
Operating cash flows from operating leases	$ 1,297	$ 833
Right of use assets obtained in exchange for operating lease obligations (1)	$ 485	$ 3,365

(1) Including the balance recognized on January 1, 2021, upon adoption of ASU No. 2016-02.

Future payments under noncancelable operating leases with initial terms of one year or more as of September 30, 2022 consisted of the following:

Years ending December 31,	
2022 (Excluding the nine months ended September 30, 2022)	$ 419
2023	1,679
2024	958
2025	34
2026	—
Thereafter	—
Total lease payments	3,090
Less: imputed interest	(108)
Total lease liabilities	$ 2,982

12. 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 such liabilities when they are known, if they are deemed probable and can be reasonably estimated. As of September 30, 2022, there were no material claims or suits outstanding.

13. STOCKHOLDERS' EQUITY

Common Stock

The holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of the Company's stockholders. The holders of common stock do not have any cumulative voting rights. Holders of common stock are entitled to receive ratably any dividends declared by the Company's board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. The Company's common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

14. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

2020 Stock Incentive Plan

In connection with the Company's IPO, the board of directors adopted, and its stockholders approved, the 2020 Incentive Award Plan (the "2020 Plan"), in order to facilitate the grant of cash and equity incentives to directors, employees (including the Company's named executive officers) and consultants of the Company and its subsidiaries. The 2020 Plan provides for the grant of stock options, including incentive stock options ("ISOs") and non-qualified stock options ("NSOs"), SARs, restricted stock, dividend equivalents, restricted stock units ("RSUs") and other stock or cash-based awards.

Stock options and stock appreciation rights under the 2020 Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). RSUs vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). As of September 30, 2022, there were 4,932,502 shares of common stock available for issuance under the 2020 Plan. The number of shares that may be issued under the 2020 Plan will automatically increase on January 1 of each year in an amount equal to the lesser of (i) 4.0% of the shares of the Company's common stock outstanding on December 31 of the preceding year or (ii) an amount determined by the Company's board of directors.

2017 Stock Incentive Plan

On August 7, 2017, the Company adopted an equity incentive plan (the "2017 Plan"). Under the 2017 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 ("SARs"), or restricted stock. Following the adoption of the 2020 Plan, no further grants have been, or will be, made under the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of outstanding awards granted under it.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2022:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2021	5,716,597	$ 22.53	8.09
Awards issued	1,533,961	$ 48.59	
Awards exercised	(457,145)	$ 10.72	
Awards forfeited	(168,758)	$ 31.42	
Awards outstanding—September 30, 2022	6,624,655	$ 29.15	7.94

Stock Appreciation Rights

The following table summarizes SARs activity for the nine months ended September 30, 2022:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2021	49,294	$ 9.24	7.29
Awards issued	—	$ —	
Awards exercised	(3,651)	$ 8.22	
Awards forfeited	(2,435)	$ 8.22	
Awards outstanding—September 30, 2022	43,208	$ 9.38	6.58

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2022:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2021	60,000	$ 29.03	9.24
Awards issued	—	$ —	
Awards exercised	—	$ —	
Awards forfeited	—	$ —	
Awards outstanding—September 30, 2022	60,000	$ 29.03	8.49

As of September 30, 2022 and December 31, 2021, stock awards issued under the 2017 and 2020 Plans of 1,753,234 and 1,285,432 common shares, respectively, were vested.

Value of Stock Options and SARs

The Company values options and SARs using the Black-Scholes option-pricing model. The Company lacks sufficient historical company-specific volatility information. Therefore, the Company estimates 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. For SARs, the expected term is based upon the weighting of certain future events. 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. An expected dividend yield of 0% is based on the fact that the Company has never paid cash dividends and does not expect to do so in the foreseeable future.

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

	As of	
	September 30, 2022	December 31, 2021
Dividend yield	0.00 %	0.00 %
Expected volatility	72.57-76.33 %	60.00 %
Risk-free interest rate	1.99 - 4.05 %	0.66 - 1.44 %
Expected term (years)	3.4 - 6.3	4.1- 6.3

Value of RSUs

The fair value of RSUs is equal to the value of the Company's common stock on the grant date.

The weighted average per share fair value of awards issued under the 2017 Plan and 2020 Plan was $17.60 and $12.82 on September 30, 2022 and December 31, 2021, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense, net for the three and nine months ended September 30, 2022 and 2021, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income in the following line items:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expense	$ 522	$ 579	$ 1,866	$ 1,548
Sales and marketing expense	1,096	852	2,956	2,248
General and administrative expense	5,349	3,233	14,412	7,926
	$ 6,967	$ 4,664	$ 19,234	$ 11,722

Stock-based compensation expense, net related to Options and RSUs issued under the 2017 Plan and 2020 Plan is included in stockholder's equity, and a liability for SARs is included in other non-current liabilities, in the Company's unaudited condensed consolidated balance sheet. As of September 30, 2022, the total unrecognized stock-based compensation expense related to Options and RSUs was $83,981. Such amount will be recognized in the Company's consolidated statement of operations over a weighted average period of 3.1 years.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan ("ESPP") was adopted by the Company's Board of Directors on April 30, 2021. The ESPP permits eligible employees to purchase shares of the Company's common stock at a 15% discount from the lesser of the fair market value per share of the Company's common stock on the first day of the offering period or the fair market value of the Company's common stock on the purchase date. Funds are collected from employees through after-tax payroll deductions. The total number of shares reserved for issuance under the ESPP was initially 629,805, which will automatically increase on January 1 of each year in an amount equal to the lesser of (i) 1.0% of the shares of the Company's common stock outstanding on December 31 of the preceding year or (ii) an amount determined by the Company's board of directors. It is

intended that the ESPP meet the requirements for an “employee stock purchase plan” under Section 423 of the Internal Revenue Code. For both the three and nine months ended September 30, 2022, there were 14,889 shares issued under the ESPP. There were no shares issued under the ESPP for the three and nine months ended September 30, 2021. The discount on the ESPP was $86 and $60 for the three months ended September 30, 2022 and 2021, respectively, and $271 and $80 for the nine months ended September 30, 2022 and 2021, respectively, and is recorded within stock-based compensation expense.

15. EARNINGS PER SHARE

Basic earnings per share is calculated by dividing net income by the weighted average number of shares of common stock outstanding. Diluted net income per common share is computed under the treasury stock method by using the weighted average number of shares of common stock outstanding, plus, for periods with net income, the potential dilutive effects of stock options, stock appreciation rights, restricted stock units and warrants.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator				
Net income	$ 87,943	$ (9,620)	$ 132,959	$ 11,883
Denominator				
Net income per common share - basic	$ 1.48	$ (0.17)	$ 2.25	$ 0.21
Net income per common share - diluted	$ 1.44	$ (0.17)	$ 2.18	$ 0.20
Weighted average number of shares of common stock - basic	59,234,720	57,722,163	59,070,063	57,188,101
Weighted average number of shares of common stock - diluted	61,207,625	57,722,163	60,921,482	58,776,158

Securities outstanding that are included in the computation above, utilizing the treasury stock method are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options, SARs, and RSUs to purchase common stock	1,972,905	—	1,851,419	1,405,092
Warrants	—	—	—	182,965
Total	1,972,905	—	1,851,419	1,588,057

Potential common shares issuable that were excluded from the computation of diluted weighted-average shares outstanding excluded from the numerator, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options, SARs, and RSUs to purchase common stock	4,754,958	6,085,742	4,876,444	4,680,651

16. INCOME TAXES

As of September 30, 2022 and December 31, 2021, our deferred tax assets were primarily the result of acquired in-process research and development costs, operating loss carryforwards, deferred research and development costs, disallowed interest, inventory, and accrued rebates. A valuation allowance of $96,366 was recorded against our net deferred tax asset balance as of December 31, 2021. We recorded a tax benefit of $74,474 as a discrete item in the three and nine months ended September 30, 2022 related to the release of a

valuation allowance on certain deferred tax assets, net, which had accumulated through December 31, 2021. We also recorded a tax benefit of $21,892 as a component to our current year effective tax rate in the three and nine months ended September 30, 2022, related to deferred tax assets, net which were utilized in the current period.

As of each reporting date, the Company considers new evidence, both positive and negative, that could affect its view of the future realization of deferred tax assets. As of September 30, 2022, in part because in the current quarter we achieved three years of cumulative pretax income, which is a positive indication of the Company's ability to generate sufficient future taxable income, the Company determined that there was sufficient positive evidence to conclude that it is more likely than not that additional deferred taxes are realizable and, therefore, released the valuation allowance accordingly.

17. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon Biosciences, LLC ("Paragon"). The related party is an entity that shares common ownership with the Company. In addition, the Chairman of the Company's board of directors was the President and owner of the entity. The Company terminated the management agreement upon the consummation of its IPO. The Company is also party to a right of use agreement with the related party whereby it has access to and the right to use certain office space leased by the related party in Chicago, Illinois. In addition, the Company had participated in certain transactions with separate related parties that also share common ownership with the Company, primarily related to combined employee health plans. The Company incurred $71 for each of the three months ended September 30, 2022 and 2021, and $213 for each of the nine months ended September 30, 2022 and 2021, in 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 of September 30, 2022 and December 31, 2021, there were no amounts due to or due from related parties included in the unaudited condensed consolidated balance sheets.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, the anticipated impact of the COVID-19 pandemic on our business, business strategy, products, prospective products, product approvals, research and development costs, anticipated timing and likelihood of success of clinical trials, expected timing of the release of clinical trial data, the plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied 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 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 agreements with Bioprojet Société Civile de Recherche ("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 additional financing needs;
- our ability to identify and/or acquire 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 some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the section in our most recent Annual Report on Form 10-K entitled “Item 1A. Risk Factors” and the sections in this Quarterly Report on Form 10-Q titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

Unless otherwise indicated, information contained in this Quarterly Report on Form 10-Q 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.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used herein, the terms “Harmony,” “we,” “us,” “our” and “the Company” refer to Harmony Biosciences Holdings, Inc., a Delaware corporation and our operating subsidiary, Harmony Biosciences, LLC.

Company Overview

We are a commercial-stage, pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action (“MOA”) specifically designed to increase histamine signaling in the brain by binding to H_3 receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of excessive daytime sleepiness (“EDS”) in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. In October 2020, WAKIX was

approved by the FDA for the treatment of cataplexy in adult patients with narcolepsy. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration (the "DEA").

Regarding pediatric narcolepsy and a pediatric indication for WAKIX, our partner, Bioprojet, has completed a Phase 3 trial in pediatric patients with narcolepsy. Bioprojet recently submitted the data to the European Medical Agency ("EMA") seeking approval for a pediatric narcolepsy indication. The EMA's decision on Bioprojet's pediatric narcolepsy submission is expected in the first quarter of 2023 and could help inform our strategy toward submitting the data to the FDA. In the meantime, we are committed to obtaining pediatric exclusivity for WAKIX and submitted a request for a pediatric written request this quarter.

We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological diseases that are mediated through H_3 receptors and histamine signaling. We are taking a mechanism-based approach to managing the life cycle of pitolisant and have identified idiopathic hypersomnia ("IH"), another central disorder of hypersomnolence like narcolepsy, as our next potential new indication for WAKIX. In April, we initiated a Phase 3 registrational trial (the "INTUNE Study") to evaluate the efficacy and safety of pitolisant in adult patients with IH and have seen good momentum in patient enrollment, with over 70% of the targeted clinical trial sites activated. We are focusing our development efforts on other rare neurological disorders in which EDS is a prominent symptom, including Prader-Willi Syndrome ("PWS") and myotonic dystrophy, otherwise known as dystrophia myotonica ("DM"). We recently received the initial topline data from our Phase 2 proof-of-concept clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS. The topline data showed a positive signal on the primary outcome related to EDS and we look forward to receiving the full data set, which will inform our understanding of the data as we plan to advance our development program in patients with PWS. In June 2021, we initiated a Phase 2 proof-of-concept clinical trial to evaluate pitolisant for the treatment of EDS, fatigue and cognitive dysfunction in adult patients with DM1 and anticipate topline results from this trial in 2023.

We also seek to expand our pipeline through the acquisition of additional assets that focus on addressing the unmet needs of patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs. We are targeting assets that will allow us to further leverage the expertise and infrastructure that we have successfully built at Harmony so we can optimize the benefit of internal synergies. Consistent with this objective, on July 31, 2022, we entered into a License and Commercialization Agreement (the "2022 LCA") with Bioprojet whereby we obtained exclusive rights to manufacture, use and commercialize one or more new products based on pitolisant in the United States and Latin America, with the potential to add additional indications and formulations upon agreement of both parties.

In addition, on August 4, 2021, we acquired HBS-102, a Melanin-concentrating hormone receptor 1 (MCHR1) antagonist previously developed as CSTI-100/ALB-127258(a)/ALB-127258 (the "Compound"), along with intellectual property and other assets related to the development, manufacture, and commercialization of the Compound from ConSynance Therapeutics, Inc. In connection with the acquisition, we made an upfront payment of $3.5 million and will be required to make certain payments upon the achievement of certain development milestones, regulatory milestones, and sales milestones and pay ongoing royalties upon commercialization. We acquired full development and commercialization rights globally, but we have provided a grant-back license to ConSynance for the development and commercialization of the Compound in Greater China. We have recently initiated a preclinical proof-of-concept study to assess the effect of HBS-102 on hyperphagia, weight gain, and other metabolic parameters in a mouse model of PWS.

Pitolisant was developed by Bioprojet and approved by the EMA in 2016 for the treatment of narcolepsy in adult patients with or without cataplexy and in 2021 for the treatment of EDS in adult patient with obstructive sleep apnea. We acquired an exclusive license to develop, manufacture and commercialize pitolisant in the United States pursuant to our license agreement with Bioprojet (as amended, the "2017 LCA") in July 2017. Pitolisant was granted Orphan Drug Designation for the treatment of narcolepsy by the FDA in 2010. It received Breakthrough Therapy designation for the treatment of cataplexy in patients with narcolepsy and Fast Track status for the treatment of EDS and cataplexy in patients with narcolepsy in April 2018.

Our operating subsidiary, Harmony Biosciences, LLC, was formed in May 2017. We were formed in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and we converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017. In February 2020, we changed our name to Harmony Biosciences Holdings, Inc. Our operations to date have consisted of building and staffing our organization, acquiring the rights to pitolisant, raising capital, opening an investigational new drug applications ("IND") for pitolisant in narcolepsy, conducting an Expanded Access Program ("EAP") for pitolisant for appropriate patients with narcolepsy in the United States, preparing and submitting our NDA for pitolisant, gaining NDA approval for WAKIX for the treatment of EDS or cataplexy in adult patients with narcolepsy, and launching and commercializing WAKIX in the United States. In addition, we have opened INDs for the development of WAKIX/pitolisant in PWS, DM and IH and have initiated clinical trials in pursuit of potential new indications in those rare disease patient populations.

Commercial Performance Metrics

As of September, 30 2022, we continue to see growth in unique healthcare professional ("HCP") prescribers of WAKIX. The average number of patients on WAKIX for the three months ended September 30, 2022 was approximately 4,600. Additionally, as of September 30, 2022, we have secured formulary access for more than 80% of all insured lives (Commercial, Medicare and Medicaid) in the United States. Within these covered lives, we have observed favorable access to WAKIX subsequent to the expanded approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020.

COVID-19 Business Update

During the COVID-19 pandemic, we developed a response strategy that included establishing cross-functional response teams and implementing business continuity plans to manage the impact of the pandemic on our employees, patients, HCPs, and our business.

Despite our response strategy, the COVID-19 pandemic has had an effect on our business and the pharmaceutical industry in general. Although the pandemic has impacted the way stakeholders interact with one another, we have leveraged technology and virtual engagement initiatives to offset our reduced in-person access to HCPs. The COVID-19 pandemic also led to high unemployment and corresponding loss of medical insurance for many patients, caused a change in relationship dynamics between patients and their HCPs, and impacted the way patients took, or did not take, their medication. As a result, we were not able to adequately gauge our growth rate and believe that our growth may be adversely impacted in the future if there is a reemergence or future outbreak of COVID-19, including any COVID-19 variant.

We intend to maintain meaningful engagement, generate awareness and educate our patients, HCPs and payors to support our commercial performance.

Commercialization

With respect to our commercialization activities, we believe the COVID-19 pandemic has put pressure on top-line prescription demand for WAKIX, primarily due to (i) our field sales team's reduced ability to access HCPs in person, and (ii) fewer patients seeing HCPs for prescriptions or treatments. The impact on demand for WAKIX may have also been 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 (i) cancelled appointments and (ii) the reprioritization of healthcare resources toward the treatment of COVID-19, both of which lead to fewer prescriptions. Despite these challenges, we continued to engage and educate HCPs virtually on the overall benefit/risk profile of WAKIX and continued to provide support for people living with narcolepsy. As offices, clinics and institutions have increased in-person interactions pursuant to health authority and local government guidelines, our field teams are re-initiating in-person interactions with HCPs and customers, but the timing and level of engagement may vary by account and region and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19, including the rise of variants, may occur. Access to HCPs for our sales team is still limited and despite the opening up of the economy, we are still in a transition

phase and expect continued, but decreasing, pressure on top line demand in future quarters as the challenges presented by COVID-19 begin to subside.

During the pandemic, elevated unemployment and the corresponding loss of health insurance caused some eligible patients to shift from commercial insurance to free drug and patient assistance programs, which impacted our ability to convert demand into revenue. Given the high unemployment rates and resulting loss of employer-sponsored insurance coverage, some patients also shifted from commercial payor coverage to government payor coverage, which may have impacted, and may continue to impact, our net revenue.

Supply Chain

We currently expect to have adequate supply of WAKIX into the first quarter of 2024, with additional API on-hand inventory to support at least 36 months beyond this time frame. We continue to work 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. We believe that our access to the required production lines to produce additional API and WAKIX finished product throughout the next 12 to 18 months would not be significantly impacted should there be a need to reprioritize manufacturing resources for the production of materials utilized for COVID-19 vaccines.

Our manufacturing partners in France and the United States continue to be operational. If there is a subsequent outbreak of COVID-19, or if it reemerges for an extended period of time and/or begins to impact essential distribution systems such as transatlantic freight, FedEx, UPS and postal delivery, we may experience disruptions to our supply chain and operations with associated delays in the manufacturing and supply of our products.

Research and Development

The COVID-19 pandemic has negatively impacted the pharmaceutical industry's ability to conduct clinical trials and this impact was recently accentuated with the emergence of the Omicron variant during the second half of 2021. As a result of some challenges that we have experienced due to the COVID-19 pandemic, we have taken measures and put contingency plans in place in order to advance our clinical development programs. We implemented remote and virtual approaches to clinical trials, including the ability to perform screening remotely and allow electronic signatures on informed consent forms, using telemedicine for remote clinic visits to perform efficacy assessments and sending out licensed HCPs to patients to collect safety assessments (e.g. labs, electrocardiograms) as required by the protocols. We performed and continue to perform remote site visits and data monitoring where possible. These measures were instituted with the intent of maintaining patient safety and trial continuity while preserving study integrity. One unique challenge we continue to face is the ability to access sleep labs during the COVID-19 pandemic in order to conduct objective sleep testing, which is required for some of our clinical trials. In addition, we rely on contract research organizations ("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. The COVID-19 pandemic has also affected us at the clinical trial site level due to staffing shortages and/or personnel being pulled off clinical trials to care for patients with COVID-19. In addition, the COVID-19 pandemic has resulted in a significant increase in FDA workload as well as the need to reprioritize the projects under review. As a result, we may continue to experience delays in FDA timelines along the course of the regulatory process (e.g. milestone meetings) and PDUFA action dates. If there is a subsequent outbreak of COVID-19 or any variant thereof or if it reemerges for an extended period of time in the future, we may experience significant delays in 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 evolved rapidly and caused a significant disruption of domestic and global financial markets. In addition, the pandemic limited our ability to conduct in-person due diligence and other

interactions to identify new opportunities. If there is a subsequent outbreak of COVID-19 or any variant thereof or if it reemerges for an extended period of time, we may be unable to access additional capital, which could negatively affect our ability to execute on certain corporate development transactions or other important investment opportunities.

The COVID-19 pandemic has also affected, and may continue to affect, our business operations and financial results. The extent of the impact of the COVID-19 pandemic or the potential impact of a reemergence or outbreak of the pandemic 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 common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time.

Corporate Responsibility Impact

We strive to attract and retain employees that are dedicated to keeping patients at the heart of all we do while also supporting the communities where we live and work. Our commitment toward this objective has been exemplified during the COVID-19 crisis. At the onset of the pandemic we took steps to ensure the health, safety and welfare of our employees and their families by abiding by government-issued work-from-home orders and encouraging a flexible work environment, and implementing a COVID-19 leave policy allowing for paid leave for employees affected by the virus outside of their accrued paid leave. We also made no furloughs, layoffs, or adjustments to salaries as a result of the pandemic. As pandemic-related restrictions and cases began to decline, all of our employees returned to in-person operations, with flexibility as needed, which we believe is critical to collaboration, innovation, productivity, employee well-being and engagement, and enhances our culture. We continually look for ways to support our employees in all roles across the organization in balancing their work and personal lives.

Our commitment extends beyond ensuring that our employees are supported to supporting the communities where we live and work. We have contributed to relief efforts in our local communities, to patient-focused organizations and other charitable organizations during the COVID-19 pandemic, including corporate donations, food and medical supplies and other resources. We made charitable contribution matches to local nonprofit organizations on behalf of our employees, further extending our charitable reach. We initiated our Progress at the Heart funding program to support nonprofit organizations in their efforts to address disparities, injustice and inequities in rare neurological disease diagnosis and treatment. These commitments collectively allow us to ensure that our employees are engaged in their communities in ways that make a lasting impact.

Financial Operations Overview

Revenue

Net product sales includes gross sales of WAKIX less provisions for sales discounts and allowances, which includes trade allowances, rebates to government and commercial entities, and discounts. Although we expect net sales to increase over time, the provisions for sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in our 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. Our cost of product sales is increasing moderately as we continue to ramp up production and sales infrastructure to meet expected demand for WAKIX.

The shelf life of WAKIX is three years from date of manufacture, with the earliest expiration of current inventory expected to be May 2023. We regularly review our inventory levels and expect write-offs from time to

time. We will continue to assess inventory levels in future periods as demand for WAKIX and the rate of inventory turnover evolves.

Research and Development Expenses

Research and development expenses generally include development programs for potential new indications for pitolisant in patients with IH, PWS and DM. We also incur research and development expenses related to our team of Medical Science Liaisons ("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 addition, our MSLs support our market access team with clinical data presentations to payors upon request and our clinical development team to identify potential clinical trial sites. Research and development costs are expensed as incurred. We have significantly increased our research and development efforts as we advance our clinical programs in IH, PWS and DM and assess other product candidates to expand our pipeline. Research and development expenses also 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 ("CMOs");
- manufacturing costs in connection with producing materials for use in conducting clinical trials;
- costs related to packaging and labelling of clinical supplies;
- other third-party expenses (i.e., consultants, advisors) directly attributable to the development of our product candidates; and
- amortization expense for assets used in research and development activities.

We do not track research and development expenses on an indication-by-indication basis. A significant portion of our research and development costs are external costs, such as fees paid to CROs and CMOs, central laboratories, contractors, and consultants in connection with our clinical development programs. Internal expenses primarily relate to personnel who are deployed across multiple programs.

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 indications for pitolisant, advance HBS-102 from preclinical studies into the clinic, and identify potential new product candidates to develop toward new indications.

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. There are 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, including any future resurgence or new variants, 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;
- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical programs that support 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 primarily relate to the market development and commercialization activities of WAKIX for the treatment of EDS and cataplexy in adult patients with narcolepsy. Market development and commercial activities account for a significant portion of our operating expenses and are expensed as incurred. We expect our sales and marketing expenses to increase in the near- and mid-term to support our indications for the treatment of EDS or cataplexy in adult patients with narcolepsy and to 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 payor education, specialty pharmacy programs 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, sales and marketing expenses include external costs such as website development, media placement fees, agency fees for patient, medical education and promotional expenses, market research, analysis of secondary data, conference fees and consulting fees.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our personnel in executive, legal, finance and accounting, human resources, investor relations, and other administrative departments. General and administrative expenses also consist of office leases, 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 be driven by costs associated with 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 SEC, insurance and investor relations costs. If any of our current or future indication expansion programs or new product candidates obtain U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Paragon Agreements

We were party to a management services agreement with Paragon Biosciences, LLC (“Paragon”), which was terminated upon the consummation of our IPO, pursuant to which Paragon provided us with certain professional services.

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 three and nine months ended September 30, 2022, we paid $0.1 million and $0.2 million, respectively, pursuant to this agreement.

Interest Expense, Net

Interest expense, net consists primarily of interest expense on debt facilities, amortization of debt issuance costs and amortization of premiums on our debt securities, partially offset by interest income earned on our cash and investment balances and accretion of discounts on our debt securities.

Results of Operations

The following table sets forth selected items in our unaudited condensed consolidated statements of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(In thousands)		(In thousands)	
Net product revenue	$ 117,206	$ 80,732	$ 309,547	$ 214,227
Cost of product sales	22,959	14,604	56,596	37,701
Gross profit	94,247	66,128	252,951	176,526
Operating expenses:				
Research and development	40,548	11,739	60,794	22,916
Sales and marketing	20,467	16,480	58,210	49,009
General and administrative	21,331	16,856	61,374	45,704
Total operating expenses	82,346	45,075	180,378	117,629
Operating income	11,901	21,053	72,573	58,897
Loss on debt extinguishment	—	(26,146)	—	(26,146)
Other expense (income), net	56	—	96	(15)
Interest expense, net	(3,990)	(5,429)	(12,086)	(19,783)
Net income before provision for income taxes	7,967	(10,522)	60,583	12,953
Income tax benefit (expense)	79,976	902	72,376	(1,070)
Net income	$ 87,943	$ (9,620)	$ 132,959	$ 11,883

Net Product Revenue

Net product revenue increased by $36.5 million, or 45.2%, for the three months ended September 30, 2022 and increased by $95.3 million, or 44.5%, for the nine months ended September 30, 2022, compared to the same periods in 2021. The increase in both comparable periods was due to the growth in the average number of patients on WAKIX and price increases.

Cost of Product Sales

Cost of product sales increased by $8.4 million, or 57.2%, for the three months ended September 30, 2022 and increased by $18.9 million, or 50.1%, for the nine months ended September 30, 2022, compared to the same periods in 2021. The increase in both comparable periods was due to higher sales of WAKIX. Cost of product sales is primarily comprised of the royalty to Bioprojet.

Research and Development Expenses

Research and development expenses increased by $28.8 million, or 245.4%, for the three months ended September 30, 2022, and increased by $37.9 million, or 165.3%, for the nine months ended September 30, 2022, compared to the same periods in 2021. The increase for the three months ended September 30, 2022 is primarily related to the $30 million licensing fee incurred upon entering the 2022 LCA with Bioprojet. The increase for the nine months ended September 30, 2022 is primarily driven by the $30 million licensing fee as well as increased clinical development work associated with IH, PWS and DM and increased personnel costs.

Sales and Marketing Expenses

Sales and marketing expenses increased by $4.0 million, or 24.2%, for the three months ended September 30, 2022, and increased by $9.2 million, or 18.8%, for the nine months ended September 30, 2022,

compared to the same periods in 2021. The increase in both comparable periods was primarily due to patient engagement and marketing activities driven by our commercialization of WAKIX and increased personnel costs related to sales force expansion.

General and Administrative Expenses

General and administrative expenses increased by $4.5 million, or 26.5%, for the three months ended September 30, 2022 and increased by $15.7 million, or 34.3%, for the nine months ended September 30, 2022, as compared to the same periods in 2021. The increase in both comparable periods was primarily due to an increase to stock compensation associated with new awards, an increase in intangible asset amortization as a result of the $40.0 million milestone payment upon attaining $500.0 million in life-to-date aggregate net sales of WAKIX in the United States and an increase in personnel costs.

Loss on Debt Extinguishment

There were no extinguishments of debt for the three and nine months ended September 30, 2022. Loss on debt extinguishment was $26.1 million for the three and nine months ended September 30, 2021, due to the prepayment of the Credit Agreement with OrbiMed.

Interest Expense, Net

Interest expense, net decreased by $1.4 million, or 26.5%, for the three months ended September 30, 2022 and decreased by $7.7 million, or 38.9%, for the nine months ended September 30, 2022, compared to the same periods in 2021 primarily due to lower interest rates as a result of entering into the Blackstone Credit Agreement in August 2021 as compared to our previous Credit Agreement with OrbiMed, partially offset by interest income generated from our investments and an increase to the LIBOR.

Income Taxes

Income tax benefit increased $79.1 million for the three months ended September 30 2022, and increased $73.4 million for the nine months ended September 30, 2022, as compared to the same periods in 2021. The increase in both comparable periods was primarily driven by the release of our valuation allowance against our net deferred tax assets.

Liquidity, Sources of Funding and Capital Resources

Overview

To date, we have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock; (b) borrowings under our (i) CRG Loan, (ii) our Credit Agreement with OrbiMed and (iii) our Blackstone Credit Agreement; (c) the proceeds from our IPO; and (d) the proceeds from the sale of common stock to Blackstone. From our inception through our IPO, we received aggregate proceeds of $345.0 million from sales of our convertible preferred stock. In August 2020, we completed the IPO of our common stock, in which we sold 6,151,162 shares of our common stock, including 802,325 shares of our common stock pursuant to the underwriters' over-allotment option. The shares were sold at a price of $24.00 per share for net proceeds of approximately $135.4 million. As of September 30, 2022, we had cash, cash equivalents, restricted cash and investments of $316.8 million and accumulated deficit of $320.6 million. As of September 30, 2022, we had outstanding debt of $198.0 million.

We have invested a portion of our available cash in money market funds, U.S. government and agency securities, corporate bonds and commercial paper in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit

rating of at least A-2/P-2/F2 from at least two National Recognized Statistical Rating Organizations. Our investment portfolio may be adversely impacted by future disruptions in the credit markets.

The unaudited condensed 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 believe that our anticipated cash from operating and financing activities, including as a result of potential availability under the DDTL (defined below), existing cash and cash equivalents and investments will enable us to meet our operational liquidity needs and fund our planned investing activities for the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect.

Blackstone Credit Agreement

In August 2021, we entered into the Blackstone Credit Agreement that provides for (i) a senior secured term loan facility in an aggregate original principal amount of $200.0 million (the "Initial Term Loan") and (ii) a senior secured delayed draw term loan facility in an aggregate principal amount up to $100.0 million (the "DDTL" and, together with the Initial Term Loans, the "Loans"). The DDTL was initially available to draw down through August 9, 2022. In August 2022, we entered into an agreement to extend the expiration date of the DDTL to August 9, 2023, for which we will pay a ticking fee at a rate of 1% per annum on the undrawn portion of the DDTL, which commenced on August 10, 2022. We used substantially all of the proceeds from the Blackstone Credit Agreement, and the related sale of our common stock, to repay the balance of the OrbiMed Credit Agreement.

The repayment schedule for the Initial Loan consists of quarterly $0.5 million principal payments commencing on December 31, 2021 and increasing to quarterly $5 million payments beginning on March 31, 2024, with a $145.5 million payment due on the maturity date of August 9, 2026 ("Maturity Date"). Interest is payable quarterly commencing on November 9, 2021 and continuing through the Maturity Date. The Initial Term Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%. The Loans are guaranteed by our subsidiary Harmony Biosciences, LLC.

The Blackstone Credit Agreement contains affirmative and negative covenants, including limitations on our ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Blackstone Credit Agreement contains a financial covenant that requires us to maintain at all times cash and cash equivalents in certain deposit accounts in an amount at least equal to $10.0 million. We are in compliance with all covenants as of September 30, 2022.

Agreement Related to Intellectual Property

In August 2021, we entered into an asset purchase agreement with ConSynance Therapeutics, Inc. to acquire HBS-102 (formerly "CSTI-100"), a potential first-in-class molecule with a novel mechanism of action. Under the terms of the agreement, we acquired full development and commercialization rights globally, with the exception of Greater China, for $3.5 million. Additionally, there are payments due upon the achievement of certain milestones including $1.8 million for preclinical milestones, $19.0 million for development milestones, $44.0 million for regulatory milestones and $110.0 million for sales milestones.

License Agreement

On July 31, 2022, we entered into the 2022 LCA with Bioprojet whereby we obtained exclusive rights to manufacture, use and commercialize one or more new products based on pitolisant in the United States and Latin America, with the potential to add additional indications and formulations upon agreement of both parties. We will pay an initial, non-refundable $30 million licensing fee and additional payments of up to $155 million are potentially due under the 2022 LCA upon the achievement of certain future development and sales-based milestones. In addition, there are certain payments due upon achievement of development milestones for new indications and formulations agreed upon by both parties. The 2022 LCA also requires a fixed trademark royalty and a tiered royalty based on net sales upon commercialization, which will be payable to Bioprojet on a quarterly basis. Upon closing of the 2022 LCA on September 28, 2022, the $30 million licensing fee was recorded in research and development within the unaudited condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2022.

Recent Milestone Payment

Upon FDA approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020 (the "Cataplexy Milestone Trigger Date"), we became obligated to make the $100.0 million milestone payment (the "Cataplexy Milestone Payment") to Bioprojet under the provisions of the 2017 LCA. Subsequently, in October 2020, we made a payment to Bioprojet of $2.0 million to extend the Cataplexy Milestone Payment due date to within 90 days of the Cataplexy Milestone Trigger Date. In January 2021, we made the $100.0 million Cataplexy Milestone Payment in full to Bioprojet. In addition, we made a final $40.0 million milestone payment to Bioprojet in March 2022 upon WAKIX attaining $500.0 million in life-to-date aggregate net sales in the United States.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Selected cash flow data	(In thousands)	
Cash provided by (used in):		
Operating activities	$ 117,788	$ 61,024
Investing activities	(94,937)	(100,298)
Financing activities	4,183	347

Operating Activities

Net cash provided by operating activities for the nine months ended September 30, 2022 consisted of our net income of $133.0 million adjusted for non-cash items of $81.7 million related to deferred tax assets, $17.3 million related to intangible amortization and depreciation and $19.2 million related to stock-based compensation expense. Net working capital excluding cash increased by $27.9 million, which was partially due to the accrual of the $30.0 million licensing fee associated with the 2022 LCA.

Net cash provided by operating activities for the nine months ended September 30, 2021 consisted of our net income of $11.8 million adjusted for non-cash items of $26.1 million related to loss on extinguishment of debt, $14.0 million related to intangible amortization and depreciation and $11.7 million related to stock-based compensation expense. Net working capital excluding cash decreased by $4.6 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 was $94.9 million, which was primarily attributable to a final $40.0 million milestone payment associated with the 2017 LCA and $55.6 million in purchases of debt securities, partially offset by $0.9 million in proceeds from sales and maturities of investments.

Net cash used in investing activities for the nine months ended September 30, 2021 was $100.3 million, which was primarily attributable to the $100.0 million milestone payment associated with the 2017 LCA.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was $4.2 million, which primarily consisted of $5.3 million in proceeds from exercised options offset by $1.5 million in principal payments associated with the Blackstone Credit Agreement.

Net cash provided by financing activities for the nine months ended September 30, 2021 was $0.3 million, which primarily consisted of $190.9 million in proceeds associated with the Blackstone Credit Agreement, net of issuance costs, and $29.7 million in proceeds associated with issuance of common stock to Blackstone, net of issuance costs. These proceeds were partially offset by $222.0 million in payments of principal and exit fees associated with the extinguishment of the OrbiMed Credit Agreement.

Critical Accounting 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 ("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 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 type agreements 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 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. During the quarter covered by this report, there were no material changes to the accounting policies and assumptions previously disclosed, except as disclosed in Note 3 to the unaudited condensed consolidated financial statements contained herein.

Recent Accounting Pronouncements

See Note 3 to our unaudited condensed consolidated financial statements for recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates. We invest a portion of our cash in investment-grade, interest-bearing securities. The primary objectives of our investment activities are to preserve principal, maintain liquidity and maximize total return. In order to achieve these objectives, we invest in money market funds, U.S. government and agency securities, corporate bonds and commercial paper in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least A-2/P-2/F2 from at least two National Recognized Statistical Rating Organizations. We do not have any direct investments in asset-backed securities, collateralized debt or loan obligations, or structured investment vehicles. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Based on our $235.2 million of investments in money market funds, U.S. treasury notes, corporate bonds and municipal obligations as of September 30, 2022, 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 September 30, 2022, we had $198.0 million in borrowings outstanding. The Initial Term Loan bears interest at an interest rate equal to LIBOR (subject to a 1.00% floor) plus 6.50%. Based on the $198.0 million of principal outstanding as of September 30, 2022, an immediate 10% change in the LIBOR would not have a material impact on our debt-related obligations, financial position or results of operations.

Foreign Currency Fluctuation Risk

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

Inflation Fluctuation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations for the three and nine months ended September 30, 2022 and 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2022. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

In addition to the other information included in this report, you should carefully consider the discussion of risk factors affecting the Company as set forth in Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2021, which could materially affect our business, financial condition or future results. The risks described in these reports are not the only risks facing the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, and operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Amended and Restated Certificate of Incorporation of Harmony Biosciences Holdings, Inc.	8-K	August 21, 2020	3.1
3.2	Amended and Restated Bylaws.	8-K	August 21, 2020	3.2
10.1*+	License and Commercialization Agreement dated July 31, 2022, by and between Bioprojet Societe Civile de Recherche and Harmony Biosciences, LLC.			
10.2*	Amendment No. 1 to Credit Agreement, dated as of August 2, 2022, among Harmony Biosciences, Inc., as Borrower, Harmony Biosciences, LLC, as Guarantor, the Guarantors from time to time party thereto, the Lenders from time to time party thereto, and Wilmington Trust National Association, as Administrative Agent.			
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 formatted in Inline XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity and (vi) Notes to Financial Statements, tagged as blocks of text and including detailed tags.			
104*	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101)			

* Filed herewith.

** Furnished herewith. This certification is deemed furnished, and not filed, with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Harmony Biosciences Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

\+ Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HARMONY BIOSCIENCES HOLDINGS, INC.

By:	/s/ John C. Jacobs
Name:	John C. Jacobs
Title:	President, Chief Executive Officer and Director (principal executive officer)
Date:	November 1, 2022

By:	/s/ Sandip Kapadia
Name:	Sandip Kapadia
Title:	Chief Financial Officer (principal financial officer)
Date:	November 1, 2022

Certain identified information has been omitted from this document because it is not material and would be competitively harmful if publicly disclosed, and has been marked with "[***]" to indicate where omissions have been made.

LICENSE AND COMMERCIALIZATION AGREEMENT

THIS LICENSE AND COMMERCIALIZATION AGREEMENT ("**Agreement**") dated as of July 31, 2022 ("**Signing Date**") is entered into between Bioprojet Société Civile de Recherche, an independent (privately owned) research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France (together with its Affiliates, including Bioprojet Pharma SAS and Bioprojet Europe Ltd., "**Bioprojet**") and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania, USA ("**Harmony**").

BACKGROUND

A. Bioprojet developed the pharmaceutical product Wakix® and owns or controls certain patents, know-how and other intellectual property relating to Wakix® (the "**Wakix Product**"). The Parties entered a license and commercialization agreement on July 28, 2017 whereby Bioprojet granted Harmony certain exclusive rights and licenses to commercialize the Wakix Product (the "**LCA**").

B. Harmony and Bioprojet now wish to collaborate with respect to the co-Development, Commercialization and Manufacture of two or more potential formulations or indications of the Wakix Product in the Field (each as defined below) from the Bioprojet portfolio, all on and subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

In addition to the capitalized terms defined elsewhere in this Agreement, the following terms shall have the meanings set forth below, except as otherwise provided herein.

1.1 "Affiliate" of a Party shall mean any person, corporation or other entity that, directly or indirectly, controls, is controlled by, or is under common control with such Party, as the case may be. As used in this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") shall mean the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting share capital in such person, corporation, or other entity, or by contract or otherwise.

1.2 "Active Sales" means: (i) actively approaching or engaging with specific actual or potential customers in a territory by, for instance, email, direct mail, telephone conversations visits or detailing; or (ii) actively approaching or engaging with actual or potential customers in a territory through advertisement in media or other promotions specifically targeted at any customers in that territory, including, without limitation, through social media or website activities.

1.3 "Additional Formulation" means any formulation of the Wakix Product other than its initial formulation under the LCA, [***], which the Parties may agree from time to Develop under this Agreement.

1.4 "Additional Indication" means any Indication for which a separate IND, NDA or MAA has been filed by Harmony for a Product, which the Parties may agree from time to Develop under this Agreement, other than the Target Indications.

1.5 "Annual Net Sales" means, with respect to a particular Contract Year, all Net Sales during such Contract Year.

1.6 "Anti-Corruption Laws" means all Applicable Laws, regulations, orders, judicial decisions, conventions, and international financial institution rules regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to public officials, healthcare professionals, and private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1 et seq.).

1.7 "API" shall mean the active pharmaceutical ingredient pitolisant hydrochloride (INN).

1.8 "Applicable Laws" means any law, statute, ordinance, written rule or regulation, order, injunction, judgment, decree, constitution, or treaty enacted, promulgated, issued, enforced, or entered by any governmental authority applicable to any Party or such Party's businesses, properties, or assets.

1.9 "Approved Subcontractors" shall have the meaning set forth in Section 2.2(d).

1.10 "Bioprojet Know-How" shall mean with respect to a given Product, all Know-How relating to the Product (including the Data), to the extent Controlled by Bioprojet as of the Signing Date or thereafter during the Term of this Agreement, and needed by or reasonably useful to Harmony in order for Harmony to co-Develop, Manufacture and Commercialize the Product(s) in the Harmony Territory, or perform its obligations under this Agreement and includes Bioprojet's right and interest in and to any Joint Inventions and the Collaboration IP. Notwithstanding the foregoing, Bioprojet Know-How shall in any case include all such items that are generated by or under authority of Bioprojet, or any of its Sublicensees, in connection with the Development and Commercialization of the Product(s) in the Bioprojet Territory during the Term of this Agreement.

1.11 "Bioprojet Patents" shall mean all Patents Controlled by Bioprojet as of the Signing Date or during the Term, together with all additions, divisions, continuations, substitutions, re-issues, re-examinations, registrations, patent term extensions, supplemental protection certificates, and renewals of any such Patents and Covering (a) the compositions of matter of a Product; (b) methods or processes directed to the Manufacture of a Product; or (c) methods of use, administration or formulation of a Product, including without limitation, the Patents that are listed in Exhibit 1.11 hereto and includes Bioprojet's right and interest in and to any Joint Patents.

1.12 "Bioprojet Territory" shall mean for the Product(s), all countries in the world other than the countries in the Harmony Territory.

1.13 "Business Day" means a day other than Saturday, Sunday or any day on which commercial banks located in Paris, France and New York City, New York, U.S. (as applicable) are authorized or obligated by Applicable Law to close; provided, that, for clarification, commercial banks shall not be deemed to be authorized or obligated by law to close due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in Paris, France and New York City, New York, U.S. (as applicable) generally are open for use by customers on such day.

1.14 "Calendar Quarter" shall mean each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31 provided, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first such three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall extend from the first day of such three (3)-month period until the last day of the Term.

1.15 "Claims" means all Third Party demands, claims, actions, proceedings, and liability (whether criminal or civil, in contract, tort, or otherwise) for losses, damages, reasonable legal costs, and other reasonable expenses of any nature whatsoever.

1.16 "Clearance Date" shall mean the date on which the HSR waiting period expires or is terminated.

1.17 "Clinical Studies" shall mean any clinical studies with respect to a Product, including pre-clinical and non-clinical studies comprising part of the Development Plan for a Product, Phase 1 Studies, Phase 2 Studies, Phase 3 Studies and Phase 4 Studies, or similar clinical studies prescribed by the Regulatory Authorities in a country or (where applicable) region that is not the United States.

1.18 "CMC" means chemistry, manufacturing and controls.

1.19 "CMC Development" means the CMC-related Development activities related to the composition, manufacture, and specification of a Product intended to assure the proper identification, quality, purity and strength thereof, including: site transfer, test method development and stability testing, process development, process improvements (improving product robustness or manufacturing efficiencies), drug substance development, process validation, process scale-up, formulation development, delivery system development, QA and QC development.

1.20 "Collaboration IP" shall mean all Inventions and other Know-How arising from the Parties' joint activities under this Agreement, including any Patents which claim or otherwise disclose such Inventions.

1.21 "Commercialization" shall mean, with respect to the Product(s), any and all processes and activities directed to selling, offering for sale (including any application for pricing and reimbursement approvals and more generally, any pricing, reimbursement and market access activities), distributing, detailing, marketing, advertising, promoting, storing, transporting, distributing, importing, and other commercial exploitation activities; provided, however, that Commercialization shall exclude Development and Manufacturing activities. "Commercialize" and "Commercializing" shall have their correlative meanings.

1.22 "Commercialization Plan" means a strategic commercialization plan for a Product in the Field for the Harmony Territory (which plan shall be updated on a periodic basis but no less than twice annually by the Parties).

1.23 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, that level of efforts and resources commonly dedicated in the pharmaceutical industry by a company of similar size and resources as such Party and its Affiliates to the analogous development or commercialization activities of a product of similar commercial potential and at a similar stage in its lifecycle to accomplish a similar objective under similar circumstances exercising reasonable business judgment, it being understood and agreed that, with respect to the Exploitation of a Product, such efforts shall not be less than those efforts and resources commonly used by such Party with respect to any other product owned by it or to which it has rights, which product is of similar market and economic potential as such Product, and is at a similar stage in its Development or product life as such Product.

1.24 "Confidential Information" means all Harmony Know-How, Bioprojet Know-How and other proprietary information and data of a financial, commercial, or technical nature which the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae. Notwithstanding the foregoing, the existence of, and the terms and conditions of, this Agreement shall be considered Confidential Information.

1.25 "Contract Year" shall mean each period of time comprised of four consecutive, full Calendar Quarters following the First Commercial Sale of Product by Harmony. For clarity, the first Contract Year shall mean the first four consecutive, full Calendar Quarters following the First Commercial Sale of the first Product by Harmony, the second Contract Year shall mean the immediately subsequent four Calendar Quarters, and so forth.

1.26 "Control" (including any variations such as "Controlled" and "Controlling"), in the context of trademarks, know-how, Patents and other intellectual property rights, data and/or other information or assets, shall mean that such Party or its Affiliate owns or possesses rights to such trademarks, know-how, Patents and other

intellectual property rights, data and/or other information or assets, as applicable, sufficient to grant the applicable license or sublicense under this Agreement, in each case, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

1.27 "Cover" means, with respect to a Product, that, but for a license granted to a person under a claim included in a Patent, the Exploitation of such Product in the Field in the Territory by such person would infringe, or contribute to or induce the infringement of, such claim (or, with respect to a claim that has not yet issued, would infringe such claim if it were to issue as then being prosecuted).

1.28 "Data" shall mean, subject to Section 4.9(d), any and all research data, pharmacology data, preclinical data, clinical data and/or all Regulatory Filings and/or other regulatory documentation, information and submissions pertaining to, or made in association with a IND, MAA, NDA or Regulatory Approval, for the Product(s), in each case to the extent Controlled by a Party as of the Signing Date or thereafter during the Term of this Agreement.

1.29 "Development" or "Develop" shall mean non-clinical and clinical research and drug development activities and programs, including toxicology, pharmacology, statistical analysis, Clinical Studies (including pre- and post-approval studies), regulatory affairs, and regulatory activities pertaining to designing and carrying out Clinical Studies and obtaining Regulatory Approvals (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.30 "Development Budget" means the budget of Development costs and expenses covering all Clinical Study and CMC Development activities contemplated by the applicable Development Plan for each Product, as jointly developed by the Parties (through a Working Group focussed on Development activity) and subject to approval by the JSC and including a twelve (12) month rolling forecast and such other Development costs and expenses that the Parties agree to add to such budget in writing.

1.31 "Development Cost Share" shall have the meaning set forth in Section 4.5.

1.32 "Development Milestone Payment" means the payment to be made by Harmony to Bioprojet upon the first achievement of the corresponding Development Milestone by Harmony as set forth in Section 6.2.

1.33 "Development Milestones" means the Development milestones set forth in Section 6.2.

1.34 "Development Plan" means, with respect to a given Product, the global plan for such Product in the Field (which plan shall be updated on a periodic basis but no less than annually by the JSC) covering the activities to be performed by each of the Parties (for at least three (3) years on a rolling basis) with respect to: (i) the research and Development of the Product, with the timing and scope of agreed Clinical Studies, key development milestones and associated timetable (including timing and the sequencing of Development of each Product in the Harmony Territory and the Bioprojet Territory); (ii) the then current target product profile of such Product; (iii) the preparation and submission of Regulatory Filings for the Product(s) to obtain Regulatory Approval for the Product(s) in the Harmony Territory; and (iv) obtaining, maintenance and expansion of Regulatory Approvals for the Product(s) in the Field, as applicable and each as updated and approved in accordance with this Agreement.

1.35 "Effective Date" shall mean the date on which the Closing occurs.

1.36 "EMA" shall mean the European Medicines Agency or any successor entity thereto.

1.37 [***].

1.38 "Exploit" means to Develop, have Developed, Manufacture, have Manufactured, use, have used, import, have imported, export, have exported, sell, have sold, and otherwise Commercialize or have Commercialized.

1.39 "FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.

1.40 "Field" shall mean the diagnosis, therapeutic treatment and/or prevention of (a) narcolepsy (including Type 1 (with cataplexy) and Type 2 and the sleepiness associated therewith) [***], and (b) any Additional Indication(s) which are added to the Target Indications by mutual written agreement of the Parties.

1.41 "Field Products" shall mean any pharmaceutical product which is under development for, or has received Regulatory Approval in, one or more Indications in the Field, other than the Product.

1.42 "First Commercial Sale" shall mean, with respect to a Product, the first bona fide, arm's length sale of that Product in the Harmony Territory by Harmony, its Affiliates and/or its Sublicensees to a Third Party following receipt of FDA approval of the first NDA for such Product in the Harmony Territory (in each case no earlier than the first bona fide, arm's length sale of that Product in the United States by Harmony, its Affiliates and/or its Sublicensees to a Third Party following receipt of FDA approval of the first NDA for such Product in the United States). Notwithstanding the foregoing, sales or transfers of reasonable quantities of a Product for Development, including proof of concept studies or other clinical trial purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.

1.43 "Generic Product" shall mean, with respect to a Product, any prescription pharmaceutical product other than such Product that (a) contains the API and (b) is "therapeutically equivalent" to such Product as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

1.44 "Governmental Authority" shall mean any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, region, or international community or (ii) a supranational, federal, state, province, county, city or other political subdivision thereof, including the FDA, any of which has binding jurisdiction.

1.45 "Harmony Know-How" shall mean, with respect to a given Product, all Know-How relating to the Product (including the Data), to the extent Controlled by Harmony as of the Signing Date or thereafter during the Term of this Agreement, and needed by or reasonably useful to Bioprojet in order for Bioprojet to co-Develop and Manufacture the Product(s) for Commercialization outside the Harmony Territory, to Commercialize the Product(s) outside the Harmony Territory, or perform its obligations under this Agreement and includes Harmony's right and interest in and to any Joint Inventions and the Collaboration IP. Notwithstanding the foregoing, Harmony Know-How shall in any case include all such items that are generated by or under the authority of Harmony, or any of its Affiliates or Sublicensees, in connection with the Development and Commercialization of the Product(s) in the Harmony Territory during the Term of this Agreement.

1.46 "Harmony Territory" shall mean the United States and its territories, commonwealths and protectorates (including Puerto Rico) and each of the countries of Latin America and their respective territories, commonwealths and protectorates.

1.47 "ICH Guidelines" shall mean the International Council for Harmonization guidelines, as amended from time to time.

1.48 "IND" shall mean an Investigational New Drug application (as such term is used in United States 21 C.F.R. Part 312, Subpart B) filed with the FDA for authorization to commence Clinical Studies.

1.49 "IND Acceptance" means, with respect to an IND, the earlier of (a) the date of receipt by a Party or its Affiliates of written confirmation from the FDA that human Clinical Studies may proceed under such IND in the United States, and (b) the date of the expiration of the applicable waiting period after which human Clinical Studies may proceed under such IND in the United States. Notwithstanding anything set forth herein, "IND Acceptance" shall not be deemed to have occurred in any circumstances where a Party or its Affiliate withdraws any IND filed with the

FDA for a Product at any time prior to the commencement of human Clinical Trials with such Product in the United States.

1.50 "Indication" shall mean a separate, defined, and well-categorized class of human disease, disorder, syndrome, or condition for which a separate NDA or MAA may be filed (whether or not such separate NDA or MAA is required or actually filed). For clarity, different stages of the same disease, disorder, syndrome, or condition will not be different Indications, different lines of treatment of the same disease, disorder, syndrome, or condition will not be different Indications, and the treatment or prevention of the same disease, disorder, syndrome, or condition in different populations (e.g., adult and pediatric) will not be different Indications.

1.51 "Invention" means any and all inventions and improvements, whether or not patentable, that are conceived or reduced to practice or otherwise made or discovered by or on behalf of a Party (and/or its Affiliates) (whether alone or jointly) in the performance of its obligations, or the exercise of its rights, under this Agreement, including but not limited to, processes, methods, compositions of matter, formulae, formulations, articles of manufacture, discoveries or findings, compounds, products, samples of assay components, media, designs, ideas, programs, software models, algorithms, developments, experimental works, or compilations of data, in each case relating to the Product(s).

1.52 "Joint Invention" means any Invention invented, made or discovered jointly by both Parties as further defined in Section 11.1.

1.53 "Joint Patent" means all Patents Covering patentable Joint Inventions.

1.54 "Joint Steering Committee" or "JSC" has the meaning given in Section 3.1.

1.55 "Know-How" means all technical information, know-how, documents, and Data (including datasets), including Inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise, and other technology applicable to compounds, formulations, compositions, or products, to their manufacture, development, registration, use, or commercialization, or to methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them, whether relevant to the development, manufacture, use, commercialization, or other exploitation of (including registration) of products, or which may be useful in studying, testing, development, production, or formulation of products.

1.56 "Licensed Assets" shall mean the Bioprojet Know-How, Bioprojet Patents, Product Trademarks, Product trade dress, Regulatory Filings and Regulatory Approvals and Bioprojet's right and interest in and to any Joint Inventions and Collaboration IP.

1.57 "Loss of Market Exclusivity" means, with respect to a Product on either a country-by-country or on an Indication-by Indication basis in the Territory, that the following has occurred:

(a) a Generic Product has been marketed or sold in a country in the Territory; and

(b) following such launch, net sales of such Product in any two consecutive calendar quarters are reduced by greater than 20% (twenty percent) versus the net sales of such Product for any preceding calendar quarter in the country in the Territory, other than for reasons of Product recall or shortage of supply, in the event that such Product is not Manufactured or supplied by or on behalf of Bioprojet.

1.58 "MAA" means an application for the authorization to market a pharmaceutical product in any country or group of countries outside the United States, as defined under Applicable Laws and filed with the Regulatory Authority of a given country or group of countries.

1.59 "Manufacture" means with respect to a Product, as applicable the planning, purchasing of materials for, manufacturing, producing, processing, compounding, storing, filling, packaging, labelling, leafleting, serialization, testing, quality control, quality assurance, waste disposal, and sample retention of Products and, to the extent required by applicable law and the applicable quality agreement, stability testing and release, and "Manufactured" and "Manufacturing" shall be construed accordingly.

1.60 "Material Safety Issue" shall mean that there is an unacceptable potential risk of harm to humans based upon (i) technical data; (ii) pre-clinical safety data, including data from animal toxicology studies; or (iii) the observation of adverse effects in humans following a Product (or product developed outside this Agreement using Collaboration IP) having been administered to or taken by humans.

1.61 "NDA" shall mean a New Drug Application, including all supplements and amendments thereto, for the approval of a Product by the FDA.

1.62 "NF1" means that formulation of the Wakix Product as further described in the Initial Development Plan at Exhibit 3.1(a) [***], and will be Developed by the Parties under the terms of this Agreement and "NF1" shall include such a product whilst it is at the Development stage;

1.63 "NF2" means that formulation of the Wakix Product as further described in the Initial Development Plan at Exhibit 3.1(a) [***], and will be Developed by the Parties under the terms of this Agreement and "NF2 Formulation" shall include such a product whilst it is at the Development stage;

1.64 "Net Sales" shall mean, with respect to a Product for any period, the gross amounts billed or invoiced or otherwise received for sales of such Product in the Harmony Territory to Third Parties (other than Sublicensees) by or on behalf of Harmony, its Affiliates and/or Sublicensees, as the case may be, after Regulatory Approval of the applicable Product NDA in the Harmony Territory, less the following deductions for costs incurred by Harmony, its Affiliates and/or Sublicensees in connection with sales of the Product in the Harmony Territory, to the extent solely related to the Product and calculated in accordance with United States Generally Accepted Accounting Principles ("US GAAP") and the accounting policies of Harmony to the extent consistent with the US GAAP, its Affiliates and/or Sublicensees, as the case may be, consistently applied, for external reporting:

(a) any normal and customary trade, quantity, prompt pay, cash and similar discounts or allowances (including, chargebacks and allowances but excluding payments and other amounts described in clause (f) below) actually granted, allowed or incurred in connection with the sale of the Product;

(b) any normal and customary credits, rebates and allowances granted, allowed or incurred on account of (i) the rejection or return of the Product (including wholesaler and retailer returns and returns of expired or expiring Product), (ii) price adjustments affecting the Product, (iii) billing or quantity errors or (iv) recalls of the Product;

(c) any costs actually paid to a Third Party by Harmony or its Affiliates or Sublicensees for packing, packaging, transportation, importation, postage, shipping and handling charges for the Product, and other charges relating thereto, such as insurance and customs duties, and separately identified on the invoices or other documentation maintained in the ordinary course of business by Harmony or its Affiliates or Sublicensees;

(d) any sales, excise or value added taxes, other consumption taxes, and similar compulsory payments to, or charges by, Governmental Authorities imposed on or charged to Harmony or its Affiliates or Sublicensees in connection with the sale of the Product and separately identified on the invoices or other documentation maintained in the ordinary course of business by Harmony or its Affiliates or Sublicensees;

(e) any actual bad debts actually written off by Harmony or its Affiliates or Sublicensees, as reflected in its audited financial statements for the applicable reporting period or other documentation maintained in

the ordinary course of business by Harmony or its Affiliates or Sublicensees provided that if the debt is recovered it will be included in Net Sales; and

(f) any reasonable rebates, reimbursements, fees or other payments or assistance by Harmony or its Affiliates or Sublicensees to (i) wholesalers and other non-affiliated distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, government authorities, or other institutions or health care organizations with respect to the Product; or (ii) patients and other Third Parties (including charitable foundations) arising in connection with any patient assistance, co-pay assistance or similar programs applicable to the Product under which Harmony or its Affiliates or Sublicensees provide to low income, uninsured or other patients the opportunity to obtain Harmony's pharmaceutical products at no cost or reduced cost. With respect to the calculation of Net Sales:

(i) Net Sales shall only include the value charged or invoiced on the first arm's length sale to a Third Party.

(ii) Product distributed by Harmony or its Affiliates or Sublicensees (A) for promotional or sampling purposes, without payment or for non-monetary consideration or (B) for use in Clinical Studies shall be disregarded for purposes for calculating Net Sales.

(iii) Sales between Harmony and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of the Product shall be included within the computation of Net Sales.

1.65 "Party" shall mean Bioprojet or Harmony, individually; and "Parties" shall mean Bioprojet and Harmony, collectively.

1.66 "Patent(s)" shall mean any patents and patent applications, together with all additions, divisions, continuations, continued prosecution applications, continuations-in-part, substitutions, confirmations, validations, reissues, re-examinations, registrations, patent term extensions, supplemental protection certificates, restoration and renewals of any of the foregoing.

1.67 "Phase 1 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in the EU or a country in the Harmony Territory outside the United States.

1.68 "Phase 2 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(b), or a similar clinical study prescribed by the Regulatory Authorities in the EU or a country in the Harmony Territory outside the United States.

1.69 "Phase 3 Studies" shall mean a human clinical trial that would satisfy the requirements of United States 21 C.F.R. § 312.21(c), or a similar clinical study prescribed by the Regulatory Authorities in the EU or a country in the Harmony Territory outside the United States.

1.70 "Phase 4 Studies" shall mean any study(ies) required by the FDA or other applicable Regulatory Authority to be conducted after Regulatory Approval of a Product NDA or MAA (as applicable) in the Harmony Territory as a condition to FDA or such applicable Regulatory Authority granting such Regulatory Approval.

1.71 "Product" shall mean the NF1, the NF2 and such Additional Formulations that the Parties agree from time to time pursuant to Section 4.3 that will be Developed by the Parties under the terms of this Agreement and shall include such products whilst they are at the Development stage, each of them being considered as a Product for purposes of this Agreement.

1.72 "Product Liability Claim" shall mean any Third Party Claim that is commenced or threatened against a Party alleging product liability, product defect, design, packaging or labeling defect, failure to warn, or any similar action relating to the use or safety of those Products sold by or under authority of Harmony in the Harmony Territory.

1.73 "Product Trademarks" shall mean: (a) the product-specific trademarks owned or Controlled by Bioprojet and designated by Bioprojet for use with the Product(s); and (b) any other product-specific trademarks that Bioprojet and Harmony mutually agree upon for use with the Product(s) in the Harmony Territory during the Term of this Agreement.

1.74 "Regulatory Approval" shall mean, with respect to a Product in any country or jurisdiction, any and all approvals (including any pricing and reimbursement approvals, as applicable), licenses, permits, certifications, registrations or authorizations of any Regulatory Authority necessary under applicable law in a country or other jurisdiction in order to Develop, have Developed, Commercialize and have Commercialized, Manufacture and have Manufactured, use, sell or market the Product in such country or jurisdiction.

1.75 "Regulatory Authority" shall mean the FDA or any other regulatory body with similar regulatory authority within the Harmony Territory or in any jurisdiction outside the Harmony Territory.

1.76 "Regulatory Exclusivity" shall mean any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority in the Harmony Territory, other than an issued and unexpired Patent, including any regulatory data protection exclusivity (including, where applicable, pediatric exclusivity and/or orphan drug exclusivity) and/or any exclusivity afforded by restrictions on the granting by a Regulatory Authority of regulatory approval to market a Generic Product in the Harmony Territory.

1.77 "Regulatory Filing" shall mean all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs, MAAs and NDAs.

1.78 "Royalty Term" shall mean on a Product-by-Product and a country-by-country basis the period commencing on the First Commercial Sale of that Product in a country within the Harmony Territory by Harmony or its Affiliates or Sublicensees and ending on the latest of (x) ten (10) years thereafter; (y) the last to expire Regulatory Exclusivity relating to such Product in such country within the Harmony Territory; or (z) the expiration of the last to expire issued Bioprojet Patent Covering the Manufacture, use or Commercialization of the such Product in such country within the Harmony Territory.

1.79 "Sanctions and Export Controls" means any Applicable Laws that prohibits or places restrictions on the supply of certain products, materials, equipment, technology, software, know-how and/or information to certain markets and/or that prohibits or places restrictions on other dealings (including financial transactions) with certain countries or with particular persons or organisations within certain countries.

1.80 "SOFR" means Secured Overnight Financing Rate as published by the Federal Reserve Bank of New York from time to time.

1.81 "Sublicensee" shall mean a Third Party that has been granted a right to Commercialize the Product(s) in the Harmony Territory pursuant to Section 2.2; and "Sublicense" shall mean an agreement or arrangement granting such rights. As used in this Agreement, "Sublicensee" shall not include a wholesaler or similar distributor or reseller of the Product(s) who does not market or promote the Product(s) (including, any specialty pharmacies).

1.82 "Target Indications" shall mean the diagnosis, therapeutic treatment and/or prevention of narcolepsy (including Type 1 (with cataplexy) and Type 2 and the sleepiness associated therewith) [***], and (b) any other Additional Indication(s) added to this Agreement pursuant to Section 4.3.

1.83 [***]

1.84 "Transaction Documents" shall mean the Pharmacovigilance Agreement, the Trademark License and the other agreements contemplated by and delivered pursuant to this Agreement.

1.85 "Third Party" shall mean any person, corporation, or other entity, other than Bioprojet, Harmony and their respective Affiliates.

1.86 "United States" shall mean the United States of America and its territories, commonwealths and protectorates (including Puerto Rico).

ARTICLE 2

GRANT OF LICENSES

2.1 Licenses.

(a) Exclusive Licenses. Subject to the terms and conditions of this Agreement, effective as of the Closing, Bioprojet hereby grants to Harmony exclusive licenses, with the right to grant sublicenses as provided in Section 2.2, to the Product(s) and the Licensed Assets to (i) Manufacture and/or have Manufactured the Product(s) for use or sale in the Field in the Harmony Territory, and (ii) use and/or have used, Commercialize and/or have Commercialized the Product(s) solely in the Field in the Harmony Territory, and in each case to carry out any associated medical affairs or regulatory activities therewith.

(b) Harmony Development License. Subject to the terms and conditions of this Agreement (including Harmony's rights of enforcement under Section 11.3), effective as of the Closing, Bioprojet hereby grants to Harmony a co-exclusive (with Bioprojet and its Affiliates) license, with the right to grant sublicenses as provided in Section 2.2, under the Licensed Assets, including to clinically Develop and register with Regulatory Authorities the Product(s), in the Field, in the Harmony Territory.

(c) Bioprojet License. Subject to the terms and conditions of this Agreement, effective as of the Closing, Harmony hereby grants to Bioprojet a co-exclusive (with Harmony and its Affiliates) license, under the Harmony Knowhow and Harmony's right and interest in and to any Joint Inventions, to conduct those Development activities with respect to a Product that are specifically allocated to Bioprojet in the applicable Development Plan, including to clinically Develop and register with Regulatory Authorities the Product(s), in the Field, in the Bioprojet Territory.

(d) Certain Clarifications. The rights and licenses granted to Harmony in Section 2.1(a) shall be exclusive even as to Bioprojet and its Affiliates, except that, subject to the terms and conditions herein Bioprojet retains the rights for sale and use outside the Harmony Territory. For clarity, it is understood that, subject to Article 10, nothing in Article 2 shall prevent either Party from publicizing the Product(s) as a part of its pipeline at scientific meetings, trade conferences and the like. It is understood that during the Term, subject to Harmony's rights under the LCA and without prejudice to Additional Formulations added to this Agreement pursuant to Section 4.3, Harmony shall not research, Develop or Commercialize any products containing the API other than the Product(s) and shall not conduct research as to the Product(s) or any products containing the API and shall not clinically Develop or Commercialize the Product(s) or any products containing the API otherwise than as permitted pursuant to this Agreement. Subject to the licenses and rights granted hereunder with respect to the Product(s) (including under Article 8), Bioprojet retains the right to use (and right to grant licenses to Third Parties to use) the Licensed Assets to Develop and Commercialize products containing the API outside the Harmony Territory and in the Harmony Territory when not restricted

pursuant to Section 8.4(a) including with respect to Bioprojet's [***] program. The Parties agree that activities undertaken in accordance with this Agreement shall not give rise to a breach of the LCA and, without limitation, that any Development activity, Collaboration IP, or Product Developed under this Agreement shall not be progressed, licensed, Developed, Manufactured or otherwise Commercialized (as applicable) under or pursuant to the LCA, but rather shall be progressed, licensed, Developed, Manufactured or otherwise Commercialized (as applicable) under this Agreement.

2.2 Sublicensees and subcontractors.

(a) Harmony shall have the right, in accordance with this Section 2.2, to engage: (i) its Affiliates as sublicensees of the Product(s) (including with respect to the Licensed Assets) in the Harmony Territory; or (ii) to engage a Third Party(ies) as a Sublicensee(s) of the Product(s) (including with respect to the Licensed Assets) in the Harmony Territory subject to Bioprojet's express prior written consent not to be unreasonably withheld, conditioned or delayed. Harmony may grant sublicenses to the rights and licenses granted to Harmony under Section 2.1 to such Affiliates and Third Parties solely on the terms set forth in this Section 2.2(a) and Section 2.2(b) below and, in the case of an Affiliate, solely for so long as such entity remains an Affiliate.

(b) In any event, Harmony shall ensure that each of its Affiliates to whom Harmony grants a sublicense pursuant to Section 2.2(a) and each Sublicensee is bound by a written agreement between Harmony and such Affiliate or Sublicensee, as applicable, that does not conflict with, and contains provisions as protective of the Product(s) and Bioprojet as, this Agreement. Without limiting any of Harmony's obligations under this Agreement, Harmony shall also ensure that each Affiliate to whom Harmony grants a sublicense pursuant to Section 2.2(a) and each Sublicensee expressly agrees in writing to be bound by all of Harmony's obligations under this Agreement to the extent applicable to such Affiliate or such Sublicensee.

(c) Harmony shall remain responsible for any actions of its Affiliates and Sublicensees exercising sublicense rights under this Section 2.2 with respect to the rights and licenses granted by Bioprojet to Harmony under this Agreement to the same extent as if such actions had been by Harmony itself. Promptly following the execution of each Sublicense to a Sublicensee, Harmony shall provide Bioprojet with an unredacted executed copy of such Sublicense; and Harmony shall also provide to Bioprojet an unredacted executed copy of any amendment to a Sublicense that relates to the Product(s), promptly following the execution of each such amendment.

(d) Notwithstanding that Development activity will be undertaken jointly by the Parties (and therefore subcontractors may be jointly appointed) it is recognised that each Party may need to appoint subcontractors to perform certain activities on their behalf hereunder therefore the Parties shall, promptly after the Signing Date, use good faith efforts acting reasonably to agree, through the JSC, on a list of mutually acceptable Affiliate and Third Party subcontractors (the "Approved Subcontractors") that each Party may thereafter use, without prior notice to or consent from the other Party, to perform Development and/or Manufacturing activities and/or associated regulatory matters and activities, provided that it may be reasonable for a Party to limit such approval to a specified activity or matter under this Agreement. Either Party may propose additions to such list of Approved Subcontractors for review and approval from time to time, such approval not to be unreasonably withheld, delayed or conditioned. Each Party shall remain responsible for any actions of its Approved Subcontractor(s) exercising rights under this Section 2.2 with respect to the rights and licenses granted under this Agreement to the same extent as if such actions had been by the applicable Party itself. Promptly following the execution of each agreement with an Approved Subcontractor, the appointing Party shall provide the other Party with an unredacted executed copy of such an Agreement; and an unredacted executed copy of any amendment to such an agreement, promptly following the execution of each such amendment.

2.3 Activities Outside the Harmony Territory.

(a) To the extent permitted under Applicable Law, Harmony agrees that neither it, nor any of its Affiliates, will sell or provide or engage in Active Sales of the Product(s) to any Third Party and shall not allow its Sublicensees to sell or provide the Product(s) to any Third Party, if Harmony or its relevant Affiliate or Sublicensee knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use in the Bioprojet Territory.

(b) To the extent permitted under Applicable Law, Bioprojet agrees that neither it, nor any of its Affiliates, will sell, provide or engage in any Active Sales of the Product(s) to any Third Party and shall not allow its Sublicensees to sell or provide the Product(s) to any Third Party, if Bioprojet or its relevant Affiliate or Sublicensee knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use in the Field in the Harmony Territory.

2.4 No Other Rights.

(a) Except for the rights and licenses expressly granted in this Agreement, Bioprojet retains all rights under its intellectual property, and no additional rights shall be deemed granted to Harmony by implication, estoppel or otherwise.

(b) In particular, except for the rights and licenses expressly granted in this Agreement, the rights and licenses granted to Harmony under this Agreement do not include the right to, and Harmony shall not, Develop or otherwise participate in Development activities for the Product(s) without Bioprojet's prior written approval (which may be granted through the JSC) and an agreement as to the terms and conditions of such Development and the arising results.

(c) For clarity, the licenses and rights granted to Harmony in this Agreement shall not be construed to convey any licenses or rights under the Bioprojet Patents or the Bioprojet Know-How with respect to any subject matter other than a Product and the licenses and rights granted to Bioprojet in this Agreement shall not be construed to convey any licenses or rights under the Harmony Knowhow, Joint Inventions or Collaboration IP with respect to any subject matter other than a Product.

ARTICLE 3

GOVERNANCE

3.1 Joint Steering Committee.

(a) Establishment. Within thirty (30) calendar days following the Effective Date, Bioprojet and Harmony shall establish: a Joint Steering Committee ("Joint Steering Committee" or "JSC") for this Agreement (which may be merged with the "JSC" appointed under the LCA, as appropriate) to collaborate with one another to implement and coordinate their shared and respective activities and oversee, review and coordinate the following (subject to Section 3.4):

1. the co-Development of the pre-clinical, clinical, regulatory (as relates to pre-clinical, clinical and co-Development activities), clinical Manufacturing and other strategies and activities of the Parties under this Agreement relating to the co-Development of the Product(s), including, a strategy for the co-Development of the Product(s) under this Agreement in both the Harmony Territory and the Bioprojet Territory, approval of an initial Development Plan and annexed at Exhibit 3.1(a) and a Development Budget, in each case initially prepared and provided to the JSC by a Working Group focused on Development subject to the provisions of this Article 3: and

2. the regulatory (as relates to Manufacturing activities), medical affairs, Commercialization and Manufacturing strategies and activities of the Parties under this Agreement, including, the

registration and Commercialization of the Product(s) in the Field in the Harmony Territory and in the Bioprojet Territory, subject to the provisions of this Article 3.

(b) Duties.

(i) In addition to the activities listed above (and subject to Section 3.4) the JSC shall:

1) Review and approve the clinical activities (including clinical studies/protocols) and associated regulatory activities, regulatory affairs, including as relate to Regulatory Approvals, Regulatory Filings and any related registration activities for Product(s) in the applicable Field in the Harmony Territory (and substantive amendments and updates thereto) (including from a regulatory perspective);

2) Review and approve arrangements for Development and transfer of any Manufacturing process or Third Party Manufacturing contracts from Bioprojet to Harmony with respect to each Product and Harmony's proposed Manufacturing arrangements in the applicable Field in the Harmony Territory with respect to such Product;

3) Review and approve any Clinical Studies (and any protocols thereof) intended to be conducted by or on behalf of Harmony and Bioprojet (or either of them if the Parties agree that a Clinical Study shall not be conducted jointly) with respect to the Product(s); and

4) Review the timing and the sequencing of Development of each Product in the Harmony Territory and the Bioprojet Territory, with the United States of America being the initial territory for launch of the Product(s) unless the launch in the United States of America is delayed or the Parties agree, which agreement cannot be unreasonably withheld, that the launch in any other countries coming first would have no detrimental effect on the launch in the United States of America;

5) Determine whether to terminate or discontinue Development of the Product(s) subject to and in accordance with this Agreement and determining whether to include an Additional Formulation or expand the Field to include an Additional Indication under this Agreement.

6) Review an initial Commercialization Plan and any substantive amendments, updates and other modifications thereto from time to time as provided for in this Agreement, in each case initially prepared and provided to the JSC by Harmony.

7) Review high level information relating to the development, regulatory affairs and commercialization of the Products in the Bioprojet Territory as shared by Bioprojet from time to time consistent with past practices with respect to the Wakix Product under the LCA;

8) Provide a forum for the Parties: (A) to review, discuss and agree upon, to the extent permitted by Applicable Laws and as set forth in Section 3.4, material issues pertaining to the marketing, distribution and Commercialization of each Product in the Harmony Territory and, to the extent that any such activity is reasonably likely to negatively impact the marketing, distribution, Commercialization, or the FDA-approved label of the such Product in the Harmony Territory, in the Bioprojet Territory, including, medical affairs, market access and price (to the extent permitted by Applicable Law)/branding positioning strategies for such Product and matters pertaining to Regulatory Filings and Regulatory Approvals for such Product; and (B) to discuss their respective activities with

respect to the foregoing matters, for the avoidance of doubt nothing in this Agreement will interfere with the ability of Harmony and Bioprojet to negotiate with customers the selling price for the Product(s) in the Harmony Territory and the Bioprojet Territory respectively;

9) Provide a forum for resolving matters referred to the JSC pursuant to the procedures set out in Section 3.4 below; and

10) Perform such other duties and responsibilities as are specifically assigned to the JSC in this Agreement.

3.2 Membership. The JSC shall be composed of an equal number of representatives from each of Harmony and Bioprojet (or a Bioprojet Affiliate), selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of Harmony and Bioprojet shall be three (3) representatives. Either Party may replace its respective JSC representatives (as applicable) at any time with prior written notice to the other Party; provided that the criteria for composition of the JSC set forth in the preceding sentence continues to be satisfied following any such replacement of a Party's representative on the JSC. The Parties reserve the right to establish a separate JSC structure for each Product Developed under this Agreement, each to be established on the basis of the framework set out in this Article 3.

3.3 Meetings. The JSC shall meet at least once each Calendar Quarter, or at such other intervals as agreed to by the Parties. All JSC meetings may be conducted by telephone, videoconference or in person as determined by the JSC; provided that the JSC shall meet in person at least once each calendar year, if health and safety protocols allow for such travel. Unless otherwise agreed by the Parties, all in-person meetings for the JSC shall be held on an alternating basis between Bioprojet's facilities and Harmony's facilities. Each Party shall bear its own personnel and travel costs and expenses relating to JSC meetings. With the consent of the Parties (not to be withheld unreasonably), other appropriate employee representatives of the Parties may attend the JSC meetings as non-voting observers. The Parties shall establish procedures to facilitate communications between the JSC and the Working Groups hereunder and the relevant internal committees, teams or boards within each Party in order to maximize the efficiency of the Parties' activities pursuant to this Agreement.

3.4 Decision-Making.

(a) Subject to the remainder of this Section 3.4, decisions of the JSC shall be made by unanimous vote, with at least one (1) representative from each Party participating in any vote.

(b) In the event that the JSC do not reach consensus with respect to a particular matter within five (5) business days after the matter is submitted to the applicable committee, then either Party may, by written notice to the other Party, have such matter referred to (i) Bioprojet's Chief Executive Officer on the part of Bioprojet and (ii) Harmony's Chief Executive Officer on the part of Harmony (collectively, "Senior Executives") who shall meet promptly and negotiate in good faith to attempt to resolve the dispute.

(c) If, despite such good faith efforts, the Senior Executives are unable to resolve such dispute during such meeting, then:

(i) if such dispute relates to the Commercialization Plan (other than with respect to matters that relate to any proposed reduction of the level of resources to be committed by Harmony under the Commercialization Plan, including the number of deployed sales representatives and the marketing and promotional spending, which matters shall be subject to clause 3.4(c)(vi)below), the labeling of the Product(s) (including negotiations with the FDA or other Regulatory Authority applicable to the Harmony Territory related thereto), regulatory activities or medical affairs strategies and activities in the Territory, Harmony shall have the right to cast the deciding vote on such matter;

(ii) if such dispute relates to the price/branding positioning strategy of the Product(s) in the Harmony Territory, Harmony shall have the right to cast the deciding vote on such matter;

(iii) if such dispute relates to plans for any Clinical Study intended to be conducted by or on behalf of Harmony with respect to a Product, such Clinical Study will not be conducted without Bioprojet's vote, unless such Clinical Study is required by any Regulatory Authority in the Harmony Territory so as to maintain any Regulatory Approval in the Harmony Territory;

(iv) without prejudice to Section 3.4(c)(iii), if a dispute relates to the Development and regulatory strategy of a Product in the United States, Harmony shall have the right to cast the deciding vote on such matter;

(v) without prejudice to Section 3.4(c)(iii), if a dispute relates to the Development and regulatory strategy of the Products in the European Union, Bioprojet shall have the right to cast the deciding vote on such matter;

(vi) for any other matters to be decided by the JSC including for clarity matters pertaining to any reduction to the overall level of resources to be committed by Harmony under the Commercialization Plan, no such matters shall be implemented without unanimous consent of the Parties.

(d) For clarity, neither Party shall have the right to cast a deciding vote to excuse itself from any of its obligations specifically enumerated under this Agreement.

3.5 Working Groups. From time to time, the JSC may establish and delegate duties to sub-committees or teams (each, a "Working Group") to oversee particular projects or activities within their respective authority, including clinical, regulatory, commercial, supply and pharmacovigilance. Each Working Group and its projects or activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. Any Working Group shall be composed of an equal number of representatives from each of Bioprojet and Harmony, selected by such Party, and the total number of members of each Working Group will be determined by the JSC. Each Working Group shall meet at such times and in such places as directed by the JSC. In no event shall the authority of any Working Group exceed that specified for the JSC.

3.6 Alliance Managers. Within thirty (30) calendar days following the Effective Date, each Party shall appoint a representative ("Alliance Manager") to facilitate communications between the Parties and to act as a liaison between the Parties with respect to such other matters as the Parties may mutually agree in order to maximize the efficiency of this Agreement and the collaboration hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party.

3.7 Scope of Governance. Notwithstanding the creation of the JSC, and/or any Working Group, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JSC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided in this Agreement, or the Parties expressly so agree in writing. The JSC shall not have the power to amend or modify this Agreement, and no decision of the JSC shall be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers under this Agreement and in no event shall the Alliance Managers have any power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by the JSC.

3.8 Day-to-Day Decision-Making Authority. For the avoidance of doubt, Harmony shall bear the responsibility of the Commercialization of a Product in the Harmony Territory, provided that such decisions are not inconsistent with the Commercialization Plan or the terms and conditions of this Agreement and Bioprojet shall bear

the responsibility of the Commercialization of a Product in the Bioprojet Territory, provided that such decisions are not inconsistent with the terms and conditions of this Agreement.

ARTICLE 4
DEVELOPMENT, CLINICAL, REGULATORY AND MEDICAL AFFAIRS ACTIVITIES

4.1 Development Collaboration. The Parties intend to collaborate to co-Develop, Manufacture, conduct medical affairs activities with respect to, and Commercialize the Product(s) in the Field in the Territory, in each case subject to and in accordance with the terms and conditions of this Agreement.

4.2 The Parties agree to each exercise their respective Commercially Reasonable Efforts to (i) co-Develop the Product(s) (and to support the other Party in the co-Development of the Product(s)) in each case in order to obtain and maintain Regulatory Approval for the Product(s) in accordance with the Development Plan and any Development milestones in the Development Plan, and (ii) perform any activities assigned to them under the Development Plan.

4.3 Additional Formulations and Additional Indications.

(a) Replacement/Substitution of Product. Each Party agrees that it will not (through its representatives on the JSC) unreasonably withhold, delay or condition its consent to a request from the other Party to terminate or discontinue Development of a Product and substitute a program for the Development of an Additional Formulation (on a Development timeline and for a Development Budget that the Parties shall mutually agree (each acting reasonably)) if either (A) the Development of that Product is not progressing in accordance with the Development Plan (in particular with respect to the expected launch timeline for such Product), or (B), no incremental benefit or product profile beyond the label for the Wakix Product can be demonstrated to the Parties' reasonable satisfaction and expectations for intellectual property exclusivity cannot reasonably be met. The Development timetable for the Development program of any replacement or substituted Additional Formulation shall, if applicable, acknowledge the impact of any delay or failure(s) in the Development of the terminated Product. If the JSC agrees to the initiation of a Development program for such an Additional Formulation it shall forthwith constitute a "Product". No additional fees or milestone payments shall be payable under Article 6 with respect to any Product Developed pursuant to this Section 4.3(a);

4.4 Development Plan. From and after the Effective Date, the Parties shall conduct joint Development of the Product(s) in accordance with the applicable Development Plan and Development Budget approved by the JSC and establish required quality systems for GLP/GCP and compliance with GMP quality standards required by ICH Guidelines and regulatory requirements from the U.S. and EU. The JSC shall review each Development Plan and Development Budget on a periodic basis (but no less than annually) and approve updates to each Development Plan and Development Budget as it deems appropriate, provided that the Development Plan shall be designed to achieve both NDA Approval and MAA Approval in the Target Indication and that any amendment to the Development Plan or overrun that materially alters a Party's financial obligations more than fifteen percent (15%) above the Development Budget estimated for such year for research and Development of the Product(s) or in the aggregate over the Development Plan will be subject to that Party's prior written approval, and, in the absence of approval, any amounts in excess will be borne by the Party incurring those Development Costs subject to the Parties reasonably considering whether to budget and invoice such overspend in the following Contract Year or to permit Harmony to set off such amounts owed to Harmony by Bioprojet against any royalty revenue due from Harmony under Section 6.4.

4.5 Development Budget and Development Costs.

(a) Promptly after the Signing Date, and concurrently with the preparation of the Development Plan, the Parties will collaborate to prepare the Development Budget for the Development of the Product(s) in the Harmony Territory and the Bioprojet Territory, which Development Plan shall be designed to achieve both

NDA Approval and MAA Approval in the Target Indication in the Field. The Development Budget shall specify the estimated Development costs and expenses for each Calendar Year covered by such Development Budget. All Development costs and expenses incurred with respect to the CMC Development and the Clinical Studies conducted for the Product(s) for the Harmony Territory (pre-NDA Regulatory Approval and post-NDA Regulatory Approval, including FTE costs for Clinical Studies in the United States (including FTE cost for CMC-Development)) and set out in the Development Plan and incurred following the Effective Date (and for new Products introduced under the Agreement following the Effective Date, as incurred after such introduction) ("Development Costs"), will be shared on an equal basis such that each Party shall respectively bear in respect of each Product, fifty percent (50%) of such Development costs and expenses incurred by or on behalf of the relevant Parties with respect to the Clinical Studies for that Product ("Development Cost Share"), provided that, notwithstanding any other provision, the Development Costs incurred by Bioprojet pursuant to the Development Plan for the Products shall, in not event, exceed [***] USD and any Development Costs in excess shall be borne by Harmony. Bioprojet shall have final decision making authority as to the suitability for inclusion of Development Costs incurred in the European Union and Harmony shall have final decision making authority as to the suitability for inclusion of Development Costs incurred in the United States and each shall incur such costs to the standards applicable to such territory or market and to the standards required with respect to the Product(s) in such territory or market, including with respect to regulatory filings and acceptance by the applicable Regulatory Authority. Each Party will provide the other, within sixty (60) days after each Calendar Quarter, a statement for each Product showing the Development Cost share and cash settlement it requires in order to give effect to the Parties' allocation of Development Costs for such Product as set forth in this Section 4.5(a) for that prior quarter (each a "Report"). At either Party's reasonable request, an appointee from the finance team of the other Party responsible for the preparation of the other Party's Report will be reasonably available to discuss and answer questions regarding such Report.

(b) Without prejudice of Section 4.5(a), if the Reports demonstrate that the Development Cost Share is not equally allocated between the Parties in respect of that prior quarter and an amount is owed by one Party to the other pursuant to the Development Cost Share, the underfunded Party shall invoice the other Party (the "Paying Party") the amount that such other Party will bear to reconcile its portion of the Development Cost Share.

(c) The Paying Party shall make payment in full to the other Party within thirty (30) days after the date of such invoice. All payments to be made by either Party under this Section 4.5 shall be made by wire transfer in USD to the credit of such bank account as may be designated by the other Party in writing.

(d) Any undisputed payments or portions thereof due under this Section 4.5 which are not paid when due will bear interest in accordance with Section 7.1

4.6 Collaboration IP. All Collaboration IP, Data, Regulatory Filings, Regulatory Approvals, and other information generated by a Party under the Development Plan and its implementation shall be deemed jointly owned Collaboration IP for the purpose of this Agreement.

4.7 Exchange of Data and Know-How.

(a) By Bioprojet. Bioprojet or its Affiliates will in a timely fashion make available to Harmony, all Bioprojet Know-How relating to the Product(s) that exists as of the Effective Date and is necessary, or reasonably useful, for Harmony to co-Develop, Manufacture and Commercialize the Product(s) in accordance with this Agreement, including all Data from Clinical Studies and preclinical studies for the Product(s) that have been conducted by Bioprojet or its Affiliates prior to the Effective Date, in each case to the extent Controlled by Bioprojet or its Affiliates. Bioprojet shall make any such Data available in the original language in which such Data was generated, provided if such original language is not English, then Bioprojet shall provide English translations thereof.

(b) By Either Party. During the Term, each Party shall provide to the other Party all such Party's Know-How (i.e., in case of Bioprojet, Bioprojet Know-How, and in the case of Harmony, Harmony Know-How) (including, all Data from Clinical Studies and preclinical studies for the Product(s) conducted by such Party or its Affiliates during the Term of this Agreement and its respective share of any Know-How that comprises Collaboration IP) that is Controlled by such Party or its Affiliates, is generated during the Term of this Agreement, is necessary, or reasonably useful to co-Develop, Manufacture and Commercialize the Product(s) in the Field, and that has not previously been provided hereunder, in each case promptly upon its development or completion. The Party providing such Party's know-how shall provide the same in electronic form to the extent the same exists in electronic form, and shall provide copies or an opportunity to inspect (and copy) for all other materials comprising such know-how (including, for example, original patient report forms and other original source data). Any Data provided by one Party to the other under this Section 4.7(b) shall be provided in the original language in which such Data was generated, provided if such original language is not English, then the Party supplying such Data shall also provide English translations thereof. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Bioprojet Know-How and the Harmony Know-How under this Section 4.7(b).

4.8 Clinical Studies and Pre-Clinical Studies.

(a) Bioprojet and Harmony shall be jointly responsible (with input from both Parties through the JSC and otherwise) for conducting, to the best of their respective abilities, any and all additional Clinical Studies (including, any pediatric studies) and/or preclinical studies (which may, in either case, require sites in the Harmony Territory) whether pre-Regulatory Approval or post-Regulatory Approval, necessary, required or appropriate for obtaining and maintaining Regulatory Approval (including those relating to Phase 4 Studies), in each case as set forth in the Development Plan in the Harmony Territory in accordance with the Development Plan. The allocation of all other costs and expenses associated with other regulatory activities for the Product(s) to be performed in accordance with the Development Plan shall be agreed by the Parties in the Development Budget.

(b) Bioprojet shall not perform (whether directly or indirectly) any Clinical Studies of the Product(s) or other Development activities outside the Harmony Territory, that are detrimental to the co-Development, Manufacturing and/or Commercialization of the Product(s) by Harmony in the Harmony Territory and shall provide regular updates to the JSC with respect to all of its activities in the Bioprojet Territory (or any such activities undertaken on its behalf) to the extent that the same could impact the potential Development, Manufacturing and/or Commercialization of any Product(s) in the Harmony Territory or give rise to any safety concerns and shall not clinically Develop or have clinically Developed an Additional Indication or Additional Formulation without giving Harmony prior notice through the JSC.

(c) Except for (i) the co-Development activities as part of the Development Plan and if applicable the Commercialization Plan for the Product(s) within the Field after Regulatory Approval in the Harmony Territory, (ii) undertaken jointly with Bioprojet, or (iii) as otherwise expressly provided in this Agreement, Harmony shall not perform any Development activity within the Harmony Territory without obtaining the prior consent of Bioprojet, which shall not be unreasonably withheld, conditioned or delayed if such Development activity is required by the FDA or other applicable Regulatory Authority in the Harmony Territory to maintain the NDA or MAA.

4.9 Regulatory Submissions and Regulatory Approvals.

(a) Regulatory Responsibilities.

(i) Subject to Section 4.9(a)(iii) of this Agreement, effective from and after the Effective Date, Harmony shall be responsible, using Commercially Reasonable Efforts, for filing the initial NDA for each Product with the FDA (and such other Regulatory Authorities in the Harmony Territory as

it determines in its sole discretion). Bioprojet shall transfer all applicable regulatory materials required by Harmony to facilitate such filing. Notwithstanding Harmony holding the NDA in its name (or the name of its Affiliate), Bioprojet will maintain all rights as the licensor of the Product(s) and the Licensed Assets.

(ii) Subject to Section 4.8, effective from and after the Effective Date, Harmony shall be solely responsible with respect to each Product for (A) its share of the Development Cost Share and any additional costs associated with such Product's Development activities for the Harmony Territory as the Parties agree in the Development Budget, and (B) all pre-Regulatory Approval and post-Regulatory Approval costs to the extent associated with regulatory Manufacturing and Commercialization activities with respect to that Product for the Harmony Territory. Bioprojet shall be solely responsible for (A) its share of the Development Cost Share and any additional costs associated with such Product's Development activities for the Bioprojet Territory as the Parties agree in the Development Budget, and (B) all costs associated with the Development, regulatory, Manufacturing and Commercialization activities with respect to the Product(s) for the Bioprojet Territory.

(iii) Effective from and after the Effective Date, Harmony shall prepare and submit each initial NDA to the FDA with respect to the Product(s) for the Harmony Territory, including in particular with respect (A) the preparation and submission of the NDA for the Product(s) for narcolepsy (both with and without cataplexy), (B) interactions with the FDA regarding the same (including product label negotiations), and (C) seeking FDA approval of the same.

(iv) Effective from and after the Effective Date, Harmony shall have the right (but not the obligation) to take the lead, with Bioprojet's assistance, with respect to (A) the opening of an IND in the Harmony Territory to initiate an expanded access program ("EAP") in the name of Harmony and interactions with the FDA regarding the same, and (B) all negotiations with the FDA regarding the Product(s)' labeling.

(b) Ownership of Regulatory Approvals. Harmony or a Harmony Affiliate shall hold, as licensee, all Regulatory Approvals (including, all Regulatory Filings and applications for NDAs) for the Product(s)in the Field in the Harmony Territory as Licensed Assets under this Agreement in trust for Bioprojet for the Term of this Agreement.

(c) Regulatory Activities and Cooperation.

(i) The JSC shall approve the overall strategy and positioning of all material regulatory submissions and filings by Harmony in the Harmony Territory prior to their submission or filing, based upon reasonably detailed reports and summaries of such submissions and filings to be provided by Harmony. In connection with such review, each Party shall provide to the JSC such additional information regarding a proposed material regulatory filing as the other Party may reasonably request. Prior to and after grant of the initial NDA to Harmony, Bioprojet shall have the right, but no obligation, to fully participate in all material meetings, conferences and discussions by Harmony or its Affiliates with the FDA and other Regulatory Authorities in the Harmony Territory pertaining to the Product(s), including without limitation having Bioprojet representatives present at such meetings, conferences or discussions. Harmony shall provide Bioprojet with reasonable advance notice of all such meetings and other contact and advance copies of all related material documents and other relevant material information relating to such meetings or other contact.

(ii) With respect to a given Product, Harmony shall provide to Bioprojet, as well as to the JSC, advance drafts of any material documents or other material correspondence pertaining to the Product's NDA's or the Product, including any proposed labeling, that Harmony plans to submit to

the FDA or another Regulatory Authority in the Harmony Territory. The JSC and/or Bioprojet may provide comments regarding such documents and other correspondence prior to their submission, which comments Harmony shall consider in good faith. Harmony shall provide Bioprojet with copies of all material regulatory submissions it makes to, and all material regulatory correspondence it receives from, the FDA or another Regulatory Authority in the Harmony Territory pertaining to the Product's NDA's or the Product in the Harmony Territory. Notices, copies of regulatory submissions and correspondence, and other materials to be given in advance as provided in this Section 4.9(c) shall be provided at least five (5) Business Days in advance unless circumstances necessitate a shorter time period (i.e. three (3) day NDA Field alert reports, seven (7) day IND safety reports), and in any event not less than a reasonable time in advance under the circumstances.

(iii) Bioprojet shall provide to Harmony advance drafts of any material documents or other material correspondence pertaining to Product Regulatory Filings or a Product, including any proposed labeling, that Bioprojet plans to submit to EMA or any other Regulatory Authority outside the Harmony Territory, to the extent that such Product Regulatory Filings may have any adverse impact on the Commercialization of such Product in the Harmony Territory. Harmony may provide comments regarding such documents and other correspondence prior to their submission, which comments Bioprojet shall consider in good faith. Bioprojet shall provide Harmony, as well as to the JSC, with copies of all material submissions it makes to, and all material correspondence it receives from, EMA and any other Regulatory Authority pertaining to Product Regulatory Filings or such Product in the Field in Bioprojet Territory.

(d) Rights of Reference and Access to Data. Each Party shall have the right (i) to cross-reference the other Party's Regulatory Filings and Regulatory Approvals related to the Product(s) (including in the case of Harmony, the right to cross-reference Bioprojet's, its Affiliate's or its subcontractor's drug master files for such Product(s) (collectively, "DMF")), and (ii) to access such Regulatory Filings and Regulatory Approvals and any Data therein and use such Data in connection with the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such Data in its own Regulatory Filings and Regulatory Approvals for Product(s) in the Field in the Harmony Territory with respect to Harmony and in the Bioprojet Territory with respect to Bioprojet; provided, however, that the Parties expressly acknowledge and agree that, although clause (i) above grants Harmony and its Affiliates and Sublicensees the right to cross-reference the DMF and the Data therein, clause (ii) above does not authorize Harmony or its Affiliates or Sublicensees to access, or require Bioprojet to disclose, the closed portions of the DMF or the Data therein. Each Party hereby grants to the other Party a "Right of Reference," as that term is defined in United States 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliate that relates to the Product(s) for use by Harmony to Commercialize the Product(s) in the Field in the Harmony Territory pursuant to this Agreement or by Bioprojet to Develop or Commercialize the Product(s) in the Bioprojet Territory. Each Party or such Affiliate(s) thereof shall provide a signed statement to this effect, if requested by the other Party, in accordance with United States 21 C.F.R. § 314.50(g)(3) or its equivalent as required in any other country or region or otherwise provide appropriate notification of such right of the other Party to the applicable Regulatory Authority in the Harmony Territory or the Bioprojet Territory, as the case may be.

(e) Disclaimer. Other than as expressly set forth in this Agreement, any Data disclosed by a Party to the other Party under this Agreement is provided on an "as is" basis, without any warranty (express or implied) of any kind, and the disclosing Party expressly disclaims all such warranties to the maximum extent permitted under applicable law. The receiving Party, on behalf of itself and its Affiliates and Sublicensees, accepts all risk and liability in relation to the use of the Data received from the disclosing Party under this Agreement.

4.10 Pharmacovigilance Responsibilities.

(a) During the Term:

(i) Harmony shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the Product(s) in the Harmony Territory, including filing all reports required to be filed in order to maintain any Regulatory Approvals granted for the Product(s) in the Harmony Territory (including, reporting of adverse events/adverse drug experiences, product quality complaints and safety data relating to the Product(s) in the Harmony Territory). Harmony shall promptly notify Bioprojet with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the Product(s), in the Harmony Territory. Harmony shall ensure that its Affiliates and Sublicensees comply with such reporting obligations. Harmony will allow Bioprojet, upon reasonable notice and at its own expense, to perform quality system audits at its facility, including the review of applicable documentation up to two (2) times per Contract Year.

(ii) Bioprojet shall be responsible, at its sole cost and expense, for all pharmacovigilance activities associated with the Product(s) in the Bioprojet Territory, including filing all reports required to be filed in order to maintain any Regulatory Approvals granted for the Product(s) in the Bioprojet Territory (including, reporting of adverse events/adverse drug experiences, product quality complaints and safety data relating to the Product(s) in the Bioprojet Territory). Bioprojet shall promptly notify Harmony with respect to any material changes or material issues that may arise in connection with any Regulatory Approvals for the Product(s) in the Bioprojet Territory. Bioprojet shall ensure that its Affiliates and Third Party sublicensees comply with such reporting obligations. Bioprojet shall be responsible, at its sole cost and expense, for managing and maintaining the global core data safety sheet for the Product(s) (the "Product Core Data Sheet") within and outside the Harmony Territory; and Harmony shall cooperate with and assist Bioprojet, as requested and/or as provided for in the Pharmacovigilance Agreement (as defined below), to enable Bioprojet to meet its regulatory reporting and other requirements with respect to managing and maintaining the Product Core Data Sheet within and outside the Harmony Territory.

This exchange of information shall be governed by the Safety Data Exchange Agreement ("SDEA") agreed between the Parties under the LCA, as amended by the Parties at the Effective Date or within [thirty (30) days] thereafter to incorporate the Product(s) and each Party agrees to the timely exchange of safety data as outlined in the SDEA.

(b) No later than necessary to ensure that all regulatory requirements are met, and to the extent required by Applicable Laws or any Regulatory Authority in the Harmony Territory, each Party shall establish and thereafter maintain a safety database with respect to the Product(s) in such Party's territory (i.e., in the case of Harmony, the Harmony Territory, and in the case of Bioprojet, the Bioprojet Territory), and shall provide the other Party with a duplicate copy of such safety database. The SDEA includes provisions to facilitate and ensure that each Party has sufficient information to maintain its own safety database thereafter.

4.11 Medical Affairs Responsibilities. Effective from and after the Effective Date, Harmony shall be responsible, at its sole cost and expense, for all medical affairs activities with respect to the Product(s) in the Harmony Territory and shall co-ordinate, develop and implement a medical affairs strategy with respect to each Product across the Harmony Territory and the Bioprojet Territory (including the activities listed in Sections 10.4 to 10.6), including for the pre-Regulatory Approval and post-Regulatory Approval periods.

4.12 Compliance with the Laws. Each Party shall comply in all material respects with all, and shall not violate in any material respect any, Applicable Laws with respect to the conduct of its respective business or the ownership or operation of its respective properties or assets, including the following laws, as applicable: (i) the laws composing the Medicare and Medicaid Programs, including applicable provisions of the Social Security Act (e.g., Civil Monetary Penalties Act, 42 U.S.C. § 1320a-7a, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b), (ii) (x) any other laws prohibiting rebates, kickbacks, fee-splitting or other financial incentives or inducements, including providing products or services below cost for the referral or continuation of business, and (y) the False Claims Act,

31 U.S.C. § 3729 et seq., and (iii) laws enforced by the FDA, including the FDCA and Section 21 of the C.F.R. Each Party shall comply with Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation.

ARTICLE 5

COMMERCIALIZATION AND PROMOTION

5.1 Harmony Commercialization.

(a) Harmony's Responsibility. Except as provided below, effective from and after the Effective Date, Harmony shall be responsible for, and shall control the conduct of, the Commercialization of the Product(s) in the Harmony Territory, at its expense, under and in material accordance with the then-current Commercialization Plan.

(b) Commercialization Plan.

(i) The initial plan for the Commercialization of a Product in the Field in the Harmony Territory will be provided by Harmony to Bioprojet within a reasonable period following the Signing Date (the "Initial Commercialization Plan"), and includes in reasonable detail: the number of sales representatives to be deployed, an account/physician target-specific detail and coverage plan (including "call points"), the dollar amount and allocation of planned promotional and marketing expenses, the projected dates for the First Commercial Sale of the Product(s) in the Harmony Territory, as well as an outline regarding the price and brand positioning of the Product(s), which shall be consistent with the minimum commercial diligences set forth in this Section 5.2(b).

(ii) Harmony shall prepare for the JSC's review updates of the Commercialization Plan on an ongoing basis, and in any event, the JSC shall review the then-current Commercialization Plan twice in each calendar year.

(iii) Harmony shall carry out and manage and shall cause its Affiliates and Sublicensees to carry out and manage, the Commercialization of the Product(s) in the Harmony Territory in material accordance with the then-current Commercialization Plan and the provisions of this Agreement.

5.2 Commercialization Diligence.

(a) Harmony shall use Commercially Reasonable Efforts to Commercialize a Product in the Field in the Harmony Territory and to launch such Product in the Harmony Territory with respect to the Target Indication(s) as soon as practicable, but no later than within six months following approval of applicable the Product's NDA in the United States of America (or as soon as practicable thereafter in light of sufficient Product supply in applicable trade dress).

(b) Without limiting Harmony's diligence obligation as set forth in Section 5.2(a), the Initial Commercialization Plan shall provide that Harmony shall, with respect to the Target Indications, deploy on the date of Regulatory Approval by the FDA of the first Product NDA approximately the number of sales representatives as indicated in the Initial Commercialization Plan in Exhibit 5.1, in connection with Commercialization of such Product in the Harmony Territory.

5.3 Marketing Materials. Marketing, advertising and promotional materials (the "Marketing Materials") concerning the Product(s) for use in the Harmony Territory, as well as training manuals and education and communication materials (the "Educational Materials") for sales representatives in the Harmony Territory shall be developed and prepared by Harmony, at its own expense. Any Marketing Materials, training manuals and/or Educational Materials developed and used by Harmony, its Affiliates and Sublicensees for the Product(s) in the Harmony Territory shall be consistent with the Regulatory Approval therein and the Commercialization Plan and shall

comply with all applicable laws, rules and regulations. Harmony shall keep Bioprojet reasonably informed with respect to core Marketing Materials and Educational Materials and shall provide to Bioprojet copies (in electronic form) of any material new Marketing Materials and/or Educational Materials for the Product(s) Developed by Harmony (and/or any of its Affiliates or Sublicensees) and any material changes to any such Marketing Materials and/or Educational Materials, and take into account Bioprojet's reasonable comments, including with respect to the compliance with Bioprojet's worldwide Product profile and this Section 5.3. It is agreed that each Party shall have the right to use any Marketing Materials and Educational Materials developed by the other Party for Commercialization of the Product(s) in the Field in its own territory.

ARTICLE 6

PAYMENTS

6.1 Upfront License Fee. In consideration of the licenses and rights granted to Harmony hereunder, Harmony shall pay to Bioprojet a one-time, non-creditable, non-refundable initial license fee in an amount of Thirty Million ($30,000,000) USD within thirty (30) days after receipt by Harmony of an invoice from Bioprojet, which invoice may not be issued by Bioprojet prior to the Effective Date.

6.2 Development Milestone Payments. Subject to this Section 6.2 and Article 7, in addition, Harmony shall pay to Bioprojet additional Development milestone payments as follows:

(a) a one-time, non-creditable, non-refundable payment in an amount of [***] USD upon the first NDA Regulatory Approval by the FDA for the first of the NF1 or the NF2 (or any replacement or substitute thereof approved for Development pursuant to Section 4.3(a)), to be granted NDA Regulatory Approval by the FDA;

(b) a one-time, non-creditable, non-refundable payment in an amount of [***] USD upon the NDA Regulatory Approval for the second of the NF1 or the NF2 (or any replacement or substitute thereof approved for Development pursuant to Section 4.3(a)), to be granted its first NDA Regulatory Approval by the FDA;

(c) With respect to each Additional Indication or Additional Formulation of a Product:

(i) a one-time, non-creditable, non-refundable payment in an amount of [***] USD upon the first IND Acceptance by the FDA with respect to each Additional Indication or Additional Formulation;

(ii) a one-time, non-creditable, non-refundable payment of one of the following:

1) [***]; or

2) [***],

[***].

(d) Harmony shall notify Bioprojet in writing after the first achievement by Harmony, or any of its Affiliates or Sublicensees, of each milestone set out in this Section 6.2 promptly, but in no event more than five (5) calendar days thereafter and pay any corresponding milestone payment within fifteen (15) days of such achievement.

(e) Each Development Milestone Payment shall be payable only on the first occurrence of the corresponding Development Milestone and none of the Development Milestone Payments shall be payable more than once, provided that the Development Milestone Payments set forth in Section 6.2(c) shall be paid for each Additional Indication or Additional Formulation of the Product with respect and nothing in this Agreement shall give rise to or increase any milestone payment under the LCA.

(f) The Parties acknowledge that no Development Milestone Payments, royalties or other payments shall be due with respect to the Product(s) pursuant to any other agreements between the Parties.

(g) Non-Refundable and Non-Creditable Payments. Notwithstanding the non-refundable or non-creditable nature of any payments under this Section 6.2, nothing in this Agreement shall limit either Party's rights to assert or obtain damages for breach of this Agreement, including damages calculated based on the payments made under this Agreement.

(h) No Projections. Harmony and Bioprojet acknowledge and agree that nothing in this Agreement, be construed as representing an estimate or projection of anticipated sales of a Product for use in any Indication, and that the Development milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Development milestone payments and royalty obligations in the event such Development milestones or Net Sales levels are achieved.

6.3 Royalty Payments. Subject to this Section 6.3, in further consideration of the licenses and rights granted to Harmony hereunder,

(a) during the Royalty Term and subject to Section 6.5, [***]

Annual Net Sales	Royalty Rate (% of Annual Net Sales)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Worked example: [***]

- [***]

and

(b) during the Royalty Term, [***]

(a) and (b) together the "Royalty Payments".

In addition to the Royalty Payments and in consideration for the Trademark License, following the First Commercial Sale of a Product and for twenty (20) years thereafter, Harmony shall pay to Bioprojet royalties on Annual Net Sale of Products in the Harmony Territory at a rate equal to [***] ("Trademark Royalty Payments").

6.4 Royalty Payments. Harmony shall make Royalty Payments to Bioprojet on a Calendar Quarter basis, no later than forty-five (45) days after the expiration of such Calendar Quarter, commencing with the Calendar Quarter

in which the First Commercial Sale occurs. Each such payment shall be accompanied by a report stating (i) the number of units of Product(s) sold by Harmony, its Affiliates and Sublicensees during such Calendar Quarter; (ii) Harmony's calculation of Net Sales during such Calendar Quarter; and (iii) amounts owed to Bioprojet under Section 6.3 for such Calendar Quarter. For clarity, Harmony shall have no obligation to make any Royalty Payment under this Agreement with respect to Annual Net Sales of Product(s) after the Royalty Term has expired other than the Trademark Royalty Payments. Upon expiration of the Royalty Term with respect to the a Product in the Harmony Territory, the license grants to Harmony under Section 2.1 above with respect to a Product in the Harmony Territory shall become non-exclusive, perpetual, fully-paid and non-assessable and non-royalty bearing, except for the Trademark Royalty Payments, on a country-by-country basis.

6.5 Royalty Rate Reduction for Licenses of Third Party Patent Rights. If, in the reasonable opinion of Harmony, the Commercialization of a Product in the Harmony Territory by Harmony or its Affiliates or Sublicensees infringes or is reasonably expected to infringe any Patent of a Third Party in the Harmony Territory (such right, a "Third Party Patent Right"), then, as between the Parties, Harmony shall have the right, but not the obligation, to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for Harmony or its Affiliates or Sublicensees to Commercialize the Product(s) in the Harmony Territory; provided that, except as set forth below, as between the Parties, without prejudice to the understanding that Bioprojet shall remain responsible for the payment of all royalty, milestone, and other payment obligations, if any, due to Third Parties with respect to any Bioprojet Know-How, Harmony shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such license. Bioprojet shall fully cooperate with Harmony to acquire such rights or license. If the Parties agree that the Commercialization of a Product in the Harmony Territory by Harmony or its Affiliates or Sublicensees infringes or is reasonably expected to infringe any Third Party Patent Right, and Harmony enters into an agreement with a Third Party in order to obtain a license to a Third Party Patent Right with respect to a Product that is reasonably necessary to Commercialize a Product in the Harmony Territory, Harmony shall be entitled to deduct from the Royalty Payments payable to Bioprojet under Section 6.3 in a given Calendar Quarter with respect to a Product fifty percent (50%) of any royalties paid to such Third Party in such Calendar Quarter under such agreement, solely to the extent that such royalties are triggered by sale of the Product(s), provided that it shall not reduce the royalty payable pursuant to Section 6.3 by more than 50%. For clarity, to the extent the adjustments under this Section 6.5 cover periods in which payments are due based on more than one royalty rate described in Section 6.3 for a Product, the Annual Net Sales to which such adjustments apply shall be distributed on a pro rata basis among the applicable royalty rates for the Product set forth in Section 6.3 above. Further any amount that Harmony is entitled to deduct that is reduced by the foregoing limitation of 50% on such deductions shall be carried forward and Harmony may deduct such amount from subsequent royalty payments due to Bioprojet until the full amount that Harmony was entitled to deduct absent such limitation is deducted.

ARTICLE 7

PAYMENTS; BOOKS AND RECORDS

7.1 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. Any payments or portions thereof due under this Agreement that are not paid within thirty (30) calendar days after the date such payments are due under this Agreement shall bear interest at an annualized rate equal to the US dollar SOFR interest rate at one month plus three (3) percentage point, calculated on the number of calendar days such payment is delinquent, compounded monthly and computed on the basis of a three hundred sixty five (365) day year, unless validly disputed. This Section 7.1 shall in no way limit any other remedies available to the Parties.

7.2 Currency Conversion. Unless otherwise expressly stated in this Agreement, all amounts specified in this Agreement are in USD, and all payments by one Party to the other Party under this Agreement shall be paid in USD. If any currency conversion shall be required in connection with the payment of royalties or other amounts under this Agreement, such conversion shall be calculated using the average exchange rate for the conversion of foreign

currency into USD, quoted by the Wall Street Journal for each business day of the Calendar Quarter to which such payment pertains.

7.3 Taxes.

(a) Withholding Taxes. If applicable laws or regulations require withholding by Harmony of any taxes imposed upon Bioprojet on account of any royalties or other payments paid under this Agreement, such taxes shall be deducted by Harmony as required by applicable law from such payment and shall be paid by Harmony to the proper taxing authorities. Official receipts of payment of any withholding tax shall be secured and sent to Bioprojet as evidence of such payment. The Parties shall exercise their reasonable efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any applicable tax treaty, and shall cooperate in filing any forms required for such reduction. All payments hereunder shall be made by Harmony from an entity resident in the United States or the European Union.

(b) Sales Taxes. Any U.S. sales taxes (including any consumption tax or value added tax), use tax, transfer taxes, duties or similar governmental charges required to be paid in connection with any payments by Harmony to Bioprojet hereunder shall be the sole responsibility of Harmony. In the event that Bioprojet is required to pay any such amounts, Harmony shall promptly remit payment to Bioprojet of such amounts. All foreign sales taxes, duties or similar governmental charges required in connection with any payments by Harmony to Bioprojet hereunder shall be the sole responsibility of Bioprojet. In the event that Harmony is required to pay any such amounts, Bioprojet shall promptly remit payment to Harmony of such amounts.

7.4 Records; Inspection. Each Party (the "Requesting Party") shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to the other Party (the "Audited Party") pursuant to this Agreement. Such books and records shall be kept for at least three (3) years following the end of the Calendar Quarter to which they pertain. Such records will be open for inspection by an independent auditor chosen by Requesting Party and reasonably acceptable to the Audited Party for the purpose of verifying the amounts payable by Audited Party hereunder. Such inspections may be made no more than once each calendar year, at reasonable times and on reasonable prior written notice. Such records for any particular Calendar Quarter shall be subject to no more than one inspection. The independent auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.4 shall be at the expense of Requesting Party, unless a variation or error producing an underpayment in amounts payable exceeding five percent (5%) of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by Audited Party, together with interest on such unpaid amounts at the rate set forth in Section 7.1 above.

ARTICLE 8

CERTAIN COVENANTS

8.1 Commercially Reasonable Efforts of Harmony. From and after the approval of the first NDA by the FDA, Harmony shall use Commercially Reasonable Efforts to [***].

8.2 General Communications. Harmony shall keep Bioprojet reasonably informed as to its progress and activities relating to the Commercialization of a Product for the Harmony Territory, and each Party shall keep each other reasonably informed with respect to regulatory matters and meetings with Regulatory Authorities applicable to such Commercialization, by way of updates to the JSC at its meetings and as otherwise specified in this Agreement, or as reasonably requested by a Party at any other time. In order to facilitate the Parties' exercise of their rights and fulfilment of their obligations hereunder, each Party agrees to give due consideration to any comments provided by the other Party with respect to such Commercialization of such Product for the Harmony Territory.

8.3 Exclusivity of Efforts - Harmony. During the Term of this Agreement and subject to any Applicable Laws, Harmony agrees that Harmony shall not, and shall cause its Affiliates not to, directly or indirectly, Develop, Manufacture, offer for sale (including apply for pricing and reimbursement approvals and more generally, undertake any pricing, reimbursement and market access activities), distribute, detail, market, advertise, promote, store, transport, distribute, import, or undertake other commercial exploitation activities, or file an NDA or initial Regulatory Approval with respect to, any Field Products or a product that contains or is combined with a Field Product or any derivation of a Field Product in the Bioprojet Territory or in the Harmony Territory.

8.4 Exclusivity of Efforts- Bioprojet

(a) During the Term of this Agreement, subject to any Applicable Laws, Bioprojet agrees that Bioprojet shall not, and shall cause its Affiliates not to, directly or indirectly, Develop, Manufacture, offer for sale (including apply for pricing and reimbursement approvals and more undertake any pricing, reimbursement and market access activities), distribute, detail, market, advertise, promote, store, transport, distribute, import, or undertake other commercial exploitation activities, or file an NDA or initial Regulatory Approval, in the Unites States of America (the "Covered Activities"), with respect to, the Products, any formulation of the Products or any pharmaceutical product that contains the API or salts of the API as its sole active ingredient, which is bioequivalent and substitutable for the Products from US payor or pharmacy standpoint as determined under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and regulations promulgated thereunder, including 21 C.F.R. Part 320, and applicable guidance and State pharmacy substitution regulations and practices in all therapeutic indications, to the extent that it can reasonably be established by Harmony in consultation with Bioprojet that such activities would compromise the US market for the Product in the Field.

8.5 [***]

(i) [***]

ARTICLE 9

PRODUCT SUPPLY AND DISTRIBUTION

9.1 Product Supply, Manufacturing Process Transfer.

(a) Harmony shall implement its own direct Manufacturing and supply arrangements with respect to the Product(s), but reserves the rights to subcontract manufacturing services from Bioprojet as agreed from time to time. Bioprojet shall use its Commercially Reasonable Efforts to transfer to Harmony in a timely manner any Bioprojet Know-How as relates to and is necessary for the Manufacturing process for a Product at no additional cost to Harmony.

(b) Bioprojet shall implement its own direct Manufacturing and supply arrangements with respect to the Product(s), but reserves the rights to subcontract manufacturing services from Harmony as agreed from time to time.

(c) Each Party (a "Manufacturing Party") shall, (subject to Applicable Law and the reasonable protection of commercially sensitive information) provide the other Party with any information relating to its agreements with its then current API and Product(s) suppliers (the "Current CMOs") from time to time at the request of the other Party and if the other Party so requests use its Commercially Reasonable Efforts to facilitate that other Party's entry into, direct agreements with such Current CMOs, for the supply of the API and Product(s) on substantially the same terms and conditions as those applied to the Manufacturing Party.

ARTICLE 10

CONFIDENTIALITY

10.1 Confidential Information. Except as expressly provided in this Agreement, the Parties agree that the receiving Party shall not publish or otherwise disclose, and shall not use for any purpose, any Confidential Information furnished to it by the other Party hereto pursuant to this Agreement, without the prior written consent of the disclosing Party. Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by written documentation:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure or, was developed by the receiving Party independent of disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party on a non-confidential basis by a person other than the disclosing Party, and who did not directly or indirectly receive such information from disclosing Party; or

(e) is developed by the receiving Party without use of or reference to any information or materials disclosed by the disclosing Party.

10.2 Permitted Disclosures. Notwithstanding the provisions of Section 10.1 above and subject to Sections 10.3 and 10.4 below, a receiving Party hereto may disclose the disclosing Party's Confidential Information to its Affiliates, Approved Subcontractors, licensees (with respect to Bioprojet), permitted Sublicensees (with respect to Harmony) and any other Third Parties to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement, prosecuting or defending litigation, complying with applicable laws or regulations or the rules of any public stock exchange, submitting information to tax or other Governmental Authorities. If a receiving Party is required by applicable laws or regulations to make any such disclosure of the disclosing Party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the disclosing Party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, shall use diligent efforts to secure confidential treatment of such Confidential Information of the disclosing Party prior to its disclosure (whether through protective orders or otherwise). For any other disclosures of the other Party's Confidential Information, including to Affiliates, Approved Subcontractors, licensees (with respect to Bioprojet), permitted Sublicensees (with respect to Harmony) and other Third Parties, a Party shall ensure that the recipient thereof is bound by a written confidentiality agreement as materially protective of such Confidential Information and the disclosing Party as this Article 10. For clarity, it is understood that (i) Bioprojet may use and disclose, in accordance with the foregoing, any Harmony Know-How provided to Bioprojet by Harmony in connection with the co-Development, Commercialization, Manufacturing, marketing, promotion and/or distribution of the Product(s) for the Bioprojet Territory and that Harmony may use and disclose, in accordance with the foregoing, any Bioprojet Know-How provided to Harmony by Bioprojet in connection with the co-Development, Commercialization, Manufacturing, marketing, promotion and/or distribution of Product(s) for the Harmony Territory.

10.3 Confidentiality of Agreement Terms. Each Party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement: (a) to advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners or private investors, and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement; or (b) to the extent necessary to comply

with Applicable Laws and court orders, including applicable securities laws, regulations or guidances; provided that in the case of paragraph (b) the disclosing Party shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with applicable securities laws, regulations or guidances) allow the other Party a reasonable opportunity to oppose with the body initiating the process (such as the Securities and Exchange Commission) and, to the extent allowable by Applicable law, to seek limitations on the portion of the Agreement that is required to be disclosed.

10.4 Publication of Clinical Data. Prior to publishing, publicly presenting and/or submitting for written or oral publication a manuscript, abstract or the like that includes Data from Clinical Studies with respect to a Product that has not previously published pursuant to this Section 10.4, each Party shall provide the other Party a copy thereof for its review and approval for at least thirty (30) calendar days (unless the publishing Party is required by Applicable Law to publish such information sooner). The publishing Party shall consider in good faith any comments provided by the other Party during such thirty (30) day period. In addition, the publishing Party shall, at the request of the other Party, remove any Confidential Information of that other Party therefrom, except Harmony shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety of the Product(s) that Harmony believes in good faith it is obligated or appropriate to disclose.

10.5 Scientific Papers. Without prejudice of the provisions set forth in Section 10.4, each Party through the JSC or its designee shall provide to the other, prior to submission for publication, of a draft of any articles and papers containing Confidential Information or concerning the Product(s) which have been prepared by or on behalf of such Party in the Field (each a "Scientific Paper") to be published in indexed medical and scientific journals and similar publications ("Medical Journals"). Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have fifteen (15) business days to notify the sending Party of its observations and suggestions with respect thereto (it being understood that, during such fifteen (15)-Business Day period, no submission for publication thereof shall take place) and the Parties shall discuss these observations and suggestions. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any Patent. Neither Party will publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical Journal, within ten (10) business days after the approval thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines).

10.6 Abstracts and Posters. If a Party intends to present findings with respect to the Product(s) in the Field at symposia or other meetings of healthcare professionals, or international and/or US or European congresses, conferences or meetings organized by a professional society or organization (any such occasion, a "Scientific Meeting"), to the extent permitted by applicable laws, such Party through the JSC or its designee shall provide to the other, prior to submission or presentation, as the case may be, copies of (i) all abstracts that will be submitted for publication in connection with (a) any international Scientific Meeting, in any Scientific Meeting in the European Union or in the United States and, (b) with respect to Harmony, any Scientific Meeting within or without the Harmony Territory and (c) with respect to Bioprojet, any Scientific Meeting in the Harmony Territory and in the Bioprojet Territory and (ii) all posters that will be presented at such Scientific Meeting, in each case, concerning the Product(s) which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster the receiving Party shall have five (5) business days in the case of an abstract, or ten (10) business days in the case of a poster, to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such review period, as applicable, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of (i) all final abstracts as soon as reasonably practicable after the approval of the Scientific Meeting, and (ii) all final posters accepted for publication or to be

presented five (5) business days prior to the planned publication or presentation thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). The Parties shall use good faith and Commercially Reasonable Efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

10.7 Press Releases. No Party will release a press release with respect to a Product or entry into this Agreement without the prior written approval of the other Party.

10.8 Prior Non-Disclosure Agreements. Upon execution of this Agreement, the terms of this Article 10 shall not supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties for the subject-matter of this Agreement.

ARTICLE 11

PATENT PROSECUTION AND ENFORCEMENT

11.1 Ownership of Inventions. [***] Harmony hereby grants to Bioprojet a non-exclusive, worldwide, irrevocable, royalty-free license, with the right to sublicense, under any Inventions Controlled by Harmony or any of its Affiliates or Sublicensees to make, have made, use, sell, offer for sale, import, practice and otherwise exploit the same, subject to the exclusive rights granted to Harmony under this Agreement with respect to each Product in the Harmony Territory.

11.2 Prosecution and Maintenance of Bioprojet Patents.

(a) Prosecution. As between Harmony and Bioprojet, Bioprojet shall, at its expense, have responsibility for the filing, prosecution and maintenance of all Bioprojet Patents in the Harmony Territory. Bioprojet agrees to keep Harmony generally informed of the course of patent prosecution or other proceedings with respect to the Bioprojet Patents within the Harmony Territory. Harmony shall hold all information disclosed to it under this Section 11.2 as confidential and if Bioprojet does not file, prosecute or maintain any Bioprojet Patents in the Harmony Territory then Harmony shall have the right, but not the obligation, to assume responsibility for the filing, prosecution and maintenance of such Bioprojet Patent(s) in the Harmony Territory in the name of Bioprojet and agrees to keep Bioprojet generally informed with respect thereto at Harmony's cost, provided that Harmony will have the right to offset [***] of those prosecution and maintenance costs against royalty to be paid to Bioprojet pursuant to Section 6.4. Bioprojet shall upon request provide Harmony with all reasonable assistance and cooperation in relation to such activities.

(b) Patent Term Extensions. Bioprojet shall have the right with respect to the Bioprojet Patents, and Harmony shall have the right with respect to any Patents owned or Controlled by Harmony, or its Affiliates or Sublicensees, related to a Product, to file all applications and take actions necessary to obtain patent term extensions, or similar additional or supplemental protection, with respect to such Product under statutes in the Harmony Territory, which extensions shall be owned by the Party that owns or Controls the underlying Patent. If such Party declines to pursue such patent term extensions, then the other Party shall have the right on behalf of such Party to file all such applications and take all such actions necessary to obtain such patent term extensions (or similar additional or supplemental protection) with respect to such Product. In each case, the Parties shall fully cooperate to obtain such extensions and additional protection.

11.3 Enforcement.

(a) Enforcement Actions. In the event that Bioprojet or Harmony becomes aware of actual or threatened infringement or misappropriation of any Bioprojet Patent or Bioprojet Know-How in the Harmony Territory or of the actual or intended manufacture or sale or use of an unauthorized version of a Product ("Infringing Product"), that Party shall promptly notify the other Party in writing. Harmony shall have the first right, but

not the obligation, to initiate proceedings (including by way of injunction or order for specific performance) or take other appropriate action, at its own expense, against any such Third Party and to include Bioprojet as a nominal party plaintiff and Bioprojet shall, where requested, furnish a power of attorney for such purpose or inclusion, or being named as a necessary party to, such action, provide access to relevant documents and other evidence and make its employees available at reasonable business hours. If Harmony does not initiate proceedings or take other appropriate action within ninety (90) calendar days of receipt of a request by Bioprojet to initiate an enforcement proceeding, then Bioprojet shall be entitled to initiate infringement proceedings or take other appropriate action against an Infringing Product at its own expense and to include Harmony as a nominal party plaintiff. The Party conducting such action shall have full control over its conduct, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In any event, the Parties shall assist one another and cooperate in any such litigation at the other's reasonable request.

(b) Recovery. Bioprojet and Harmony shall recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof, associated with any litigation against infringers undertaken pursuant to Section 11.3 above or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated between Harmony and Bioprojet as set forth in the following table to the extent such recovery represents damages relative to sales of Infringing Product in the Harmony Territory:

[***]

(c) Cooperation. The Parties shall keep one another informed of the status of their respective activities regarding any litigation or settlement thereof concerning the Bioprojet Patents or the Bioprojet Know-How within the Harmony Territory and shall assist one another and cooperate in any such litigation at the other's reasonable request (including being named as a party plaintiff to the extent necessary and requested by the other Party).

(d) Third Party Infringement Claims. If the production, sale or use of the any Product in the Harmony Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent infringement against Bioprojet or Harmony (or their respective Affiliates, licensees or Sublicensees) (collectively, "Infringement Actions"), such Party shall promptly notify the other Party hereto in writing. The Party subject to such Infringement Action shall have the right to direct and control the defense thereof, at its own expense with counsel of its choice; provided, however, that the other Party may participate in the defense and/or settlement thereof, at its own expense with counsel of its choice. In any event, the Party that is subject to the Infringement Action agrees to keep the other Party hereto reasonably informed of all material developments in connection with any such Infringement Action. Harmony agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect a Product or the manufacture, use or sale of a Product within or outside the Harmony Territory, without the prior written consent of Bioprojet, which shall not be unreasonably withheld, conditioned or delayed; and Bioprojet agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect a Product, or the packaging, use or sale of a Product, within the Harmony Territory, without the prior written consent of Harmony, which shall not be unreasonably withheld, conditioned or delayed.

(e) Patent Marking. Harmony agrees to mark, and have its Affiliates and Sublicensees mark, all patented Products they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the United States of America.

ARTICLE 12

TRADEMARKS

12.1 Display.

(a) Except as set forth in this Section 12.1, all packaging materials, labels and Marketing Materials for a Product shall display the Product Trademarks, as determined by Bioprojet, with the consent of Harmony, and which may include "WAKIX", and no other product-specific trademarks or branding. The Parties agree that Bioprojet shall file and maintain the Product Trademarks for use in the countries of the Harmony Territory determined by the Parties, based on strategic and economic interest, through the JSC.

(b) The Product(s) shall be sold in the Harmony Territory under the trade name of Harmony; provided, however that to the extent permissible under applicable law within the Harmony Territory, such packaging materials, labels and Marketing Materials shall also display the trade name of Bioprojet in reasonable size and prominence, as reasonably approved by Bioprojet. The trademarks of Harmony, trade dress, style of packaging and the like with respect to the Product(s) in the Harmony Territory may be determined by Harmony in a manner that is consistent with Harmony's standard trade dress and style, but shall be subject to the approval by the JSC.

12.2 Grant of License. Bioprojet hereby grants to Harmony an exclusive license to use the Product Trademarks and Bioprojet's trade name in the Harmony Territory for the marketing, sale and promotion of the Product(s) in accordance with this Agreement (the "Trademark License"), which Trademark License shall be reiterated pursuant to a separate agreement within ninety (90) days of the Effective Date. The Parties shall determine the ownership and all goodwill from the use of the Product Trademarks. Bioprojet's trade name shall vest in and inure to the exclusive benefit of Bioprojet and Harmony's trade name shall vest in and inure to the exclusive benefit of Harmony.

12.3 Registration of Trademarks. Bioprojet, or its designee, shall be responsible for filing and registering, at Bioprojet's expense and in its own name (to the extent permitted by applicable law), appropriate registrations for such Product Trademarks in the countries of the Harmony Territory as determined by the Parties through the JSC.

12.4 Recordation of Licenses. If trademark licenses or patent licenses must be recorded in the Harmony Territory, Bioprojet will, if necessary, provide to Harmony, on Harmony's written request, a separate trademark license for the Product Trademarks or patent license (as applicable) and Harmony will arrange for the recordation of such trade mark license or patent license with the appropriate governmental agency, at Harmony's expense, promptly following receipt of such license from Bioprojet. Harmony shall cooperate in the preparation and execution of such document(s).

12.5 Approval of Packaging and Promotional Materials. The Parties shall determine a process of review and approval of representative Marketing Materials, packaging and Product displaying the Product Trademarks and/or a Party's trade name for approval by the other Party prior to the first use of such Marketing Materials, packaging or Product(s) and prior to any subsequent change or addition to such Marketing Materials, packaging or Product(s).

12.6 Enforcement.

(a) If either Party becomes aware of any actual or threatened infringement of any Product Trademark in the Harmony Territory, such Party shall promptly notify the other Party in writing.

(b) Harmony shall have the first right, at its own expense, to initiate infringement proceedings or take other appropriate actions against an infringement of any Product Trademark in the Harmony Territory and/or to defend any actions or proceedings involving the Product Trademarks in the Harmony Territory, as the case may be.

(c) If Harmony does not initiate proceedings or take other appropriate action within ninety (90) calendar days after receipt of a request by Bioprojet to do so, then Bioprojet shall be entitled, at its own expense, to initiate infringement proceedings or take other appropriate action against an infringement of a Product Trademark in the Harmony Territory, or to defend any actions or proceedings involving or affecting a Product Trademark in the Harmony Territory, as the case may be.

(d) The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the Product Trademarks in the Harmony Territory nor the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

(e) In any event, the Parties shall keep one another informed of the status of their respective activities regarding any litigation in the Harmony Territory involving a Product Trademark or settlement thereof and shall assist one another and cooperate in any such litigation at the other's reasonable request (including joining as a party plaintiff to the extent necessary and requested by the other Party) and the other's expense.

(f) Harmony and Bioprojet shall recover their respective actual out-of-pocket expenses, or proportionate percentages thereof, associated with any litigation against infringers undertaken pursuant to this Section 12.6 or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated between Harmony and Bioprojet as set forth in the following table to the extent such recovery represents damages pertaining to the infringement of a Product Trademark in the Harmony Territory:

[***]

12.7 Termination of trademark license. Harmony's right to use the Product Trademarks and the Bioprojet trade name shall terminate in the Harmony Territory upon termination or expiration of the Trademark License. Harmony shall take all such steps as Bioprojet may reasonably request to give effect to the termination of the license to the Product Trademark and Bioprojet trade name in the Harmony Territory and to record any documents that may be required to evidence the termination of such license and transfer to Bioprojet all rights, goodwill, registrations, recordations and the like for such Product Trademarks.

12.8 Domain Names. The Parties shall discuss in good faith and agree upon how to handle any domain names containing the Product Trademarks.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. The term of this Agreement shall commence on the Signing Date and continue in force and effect, unless terminated earlier pursuant to Section 13.2, 13.3, 13.4, 13.5 or 13.6 below, until expiration of the last-to-expire Royalty Term (such period, the "Term"). Upon the expiration of the Term, the licenses granted to Harmony under Article 2 hereof will become non-exclusive, perpetual, irrevocable, fully paid up, non-assessable and non-royalty bearing, except where applicable for the Trademark Royalty Payments.

13.2 Termination for Material Breach. Without prejudice to the rights and remedies of the Parties under this Agreement, this Agreement may be terminated by either Party, in the event of a material breach or default by the other Party (as more fully described in this paragraph), either on a country-by county basis or a Product-by-Product, or in its entirety, by written notice provided to the breaching Party in the following manner: (i) the terminating Party shall send written notice of the material breach or material default to the breaching Party specifying the claimed

particulars of such breach in reasonable detail and its intention to terminate this Agreement in whole (which must be material in its significance to the terminating Party and have a seriously detrimental effect on the overall benefit that the innocent Party would otherwise derive from this Agreement) or in part with respect to specific countries in the Harmony Territory or specific Products, and (ii) the termination shall become effective ninety (90) days after written notice thereof was provided to the breaching Party, unless and if such material breach or default could be cured, and the breaching Party has cured any such material breach or default prior to the expiration of the ninety (90) day period.

13.3 Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within ninety (90) calendar days after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within ninety (90) calendar days thereafter.

13.4 Termination for Patent Challenge. Bioprojet shall have the right to terminate this Agreement immediately upon notice to Harmony if Harmony, its Affiliate or its Sublicensees initiates or in any material respect, participates in or facilitates any action challenging the validity of Bioprojet Patents.

13.5 Termination for Material Safety Issue. When a Party has a good faith belief that there is a Material Safety Issue with respect to a Product, that Party may (a) suspend, or require the suspension of, any activities under the Agreement impacted by the relevant Material Safety Issue with respect to such Product and (b) refer the matter to the relevant Regulatory Authority as soon as reasonably practicable (and never later than any required regulatory reporting timeline). If both Parties agree there is a Material Safety Issue or, if a Party disputes that there is a Material Safety Issue and the Regulatory Authority determines that there is a Material Safety Issue, the Regulatory Authority's decision shall be binding on the Parties and in each case either Party may terminate this Agreement in its entirety with respect to such Product.

13.6 Termination prior to the Closing Date:

(a) Bioprojet shall have the right to terminate this Agreement immediately upon notice to the other Party: (i) to the extent Bioprojet has made its HSR filing in material respect in accordance with this Agreement, if the Clearance Date does not occur, within two (2) months as from the date on which the HSR filings are made in accordance with this Agreement or (ii) if the Clearance Date has occurred but Harmony has not provided to Bioprojet the Harmony Closing Certificate.

(b) Harmony shall have the right to terminate this Agreement upon notice to Bioprojet (i) to the extent Harmony has made its HSR filing in material respect in accordance with this Agreement, and diligently seeks Clearance, if the Clearance Date does not occur, within two (2) months as from the date on which the HSR filings are made in accordance with this Agreement or (ii) if the Clearance Date has occurred but Bioprojet has not provided to Harmony the Bioprojet Closing Certificate.

ARTICLE 14

EFFECT OF TERMINATION

14.1 Accrued Obligations. The expiration or termination of this Agreement in whole or in part for any reason shall not release either Party from any liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement in whole or in part preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement.

14.2 Rights on Termination of Agreement in its Entirety. This Section 14.2 shall apply upon any termination of this Agreement in its entirety.

(a) Wind-down Period, Commercialization. To avoid disruption in the availability of a Product to patients, if this Agreement is terminated after the First Commercial Sale of the a Product in the Harmony Territory, Harmony, its Affiliates and its Sublicensees shall continue to distribute such Product, in accordance with the terms and conditions of this Agreement, in the Harmony Territory for which Regulatory Approval therefor has been obtained, until eighteen (18) months after the date on which Bioprojet notifies Harmony in writing that Bioprojet has secured an alternative distributor or licensee for a Product in the Harmony Territory, but in no event more for than thirty six (36) months after the effective date of any termination of this Agreement (the "Wind-down Period"); provided that Harmony, its Affiliates and its Sublicensees shall cease such activities, or any portion thereof, in the Harmony Territory upon sixty (60) calendar days' prior written notice by Bioprojet requesting that such activities (or portion thereof) be ceased. Notwithstanding any other provision of this Agreement, during the Wind-down Period, Harmony's and its Affiliates' and, subject to Section 14.2(f) below, Sublicensees' rights with respect to a Product (including the Product Trademarks) in the Harmony Territory shall be non-exclusive and, without limiting the foregoing, Bioprojet shall have the right to engage one or more other distributor(s) and/or licensee(s) of a Product in all or part of the Harmony Territory and Harmony shall not have any obligation to incur additional costs to distribute such Product. Any Product sold or disposed by Harmony, its Affiliates and, subject to Section 14.2(f) below, its Sublicensees in the Harmony Territory during the Wind-down Period shall be subject to applicable payment obligations under Article 6 above. Within thirty (30) calendar days after expiration of the Wind-down Period, Harmony shall notify Bioprojet of any quantity of the Product(s) remaining in Harmony's inventory and Bioprojet shall have the option, upon notice to Harmony, to repurchase any such quantities of the Product(s) from Harmony at the supply price paid by Harmony for such Product.

(b) Assignment of Regulatory Filings and Regulatory Approvals. Harmony shall assign (or cause to be assigned) to Bioprojet or its designee (or to the extent not so assignable, Harmony shall take all reasonable actions to make available to Bioprojet or its designee the benefits of) all Regulatory Filings for the Product(s) in the Harmony Territory, including any such Regulatory Filings made or owned by its Affiliates and/or Sublicensees. In each case, unless otherwise required by any Applicable Law or regulation or requested by Bioprojet, the foregoing assignment (or availability) shall be made within thirty (30) calendar days after the effective date of any termination of this Agreement. In addition, Harmony shall promptly provide to Bioprojet a copy of all Data and Harmony Know-How pertaining to the Product(s) in the Harmony Territory to the extent not previously provided to Bioprojet and Bioprojet shall have the right to use and disclose all Data and Harmony Know-How pertaining to the Product(s) following termination of this Agreement. In addition, all such Data and Harmony Know-How, to the extent specifically pertaining to the Product(s), shall be deemed Confidential Information of Bioprojet and not Confidential Information of Harmony (and will not be subject to the exclusions under Sections 10.1(a) or (e) above).

(c) Transition. Harmony shall use diligent efforts to cooperate at Bioprojet's expense (or at Harmony's expense if this Agreement is terminated for Harmony's breach) with Bioprojet, and/or its designee to effect a smooth and orderly transition in the Development, sale and ongoing marketing, promotion and Commercialization of the Product(s) in the Harmony Territory during the Wind-down Period. Without limiting the foregoing, Harmony shall, upon written request from Bioprojet, provide Bioprojet copies of customer lists, customer data and other customer information relating to the Product(s) in the Harmony Territory (except as prevented by the applicable laws and regulations relating to the protection of personal information), which Bioprojet shall have the right to use and disclose. Without limiting the foregoing, Harmony shall use diligent efforts to conduct in an expeditious manner any activities to be conducted under this Section 14.2.

(d) Licenses. Effective as of the date of expiration of the Wind-down Period, Harmony hereby grants to Bioprojet an exclusive, worldwide, royalty-free license, with the right to grant sublicenses, under any

Patents owned or Controlled by Harmony related to the Product(s) for the purposes of making, using, developing, importing, selling, distributing, marketing and promoting the Product(s).

(e) Return of Materials. Within thirty (30) calendar days after the end of the Wind-down Period upon request by Bioprojet, Harmony shall either return to Bioprojet or destroy all tangible items comprising, bearing or containing trademarks (including the Product Trademarks), trade names, patents, copyrights, designs, drawings, formulas or other Data, photographs, samples, literature, sales and promotional aids ("Product Materials") and Confidential Information of Bioprojet, that is in Harmony's possession. Effective upon the end of the Wind-down Period, Harmony shall cease to use all trademarks and trade names of Bioprojet (including the Product Trademarks) in the Harmony Territory, and all rights granted to Harmony hereunder with respect to the Product(s) in the Harmony Territory shall terminate.

(f) Sublicensees. Any contracts with Sublicensees of the Product(s) in the Harmony Territory engaged by Harmony shall, at the request of Bioprojet in its discretion, be assigned to Bioprojet to the furthest extent possible; provided that such assignment is accepted by the Sublicensee(s) in the Harmony Territory. In the event such assignment is not requested by Bioprojet or is not accepted by such Sublicensee(s), then the rights of such Sublicensees with respect to the Product(s) in the Harmony Territory shall terminate upon the termination of Harmony's rights with respect to the Harmony Territory. Harmony shall ensure that its Affiliates and such Sublicensees (if not assigned to Bioprojet pursuant to this Section 14.2(f)) shall transition all rights in and to the Product(s) back to Bioprojet in the manner set forth in this Section 14.2 as if such Affiliate or Sublicensee were named herein.

14.3 Rights on Termination of Agreement in part. The provisions of Sections 14.2(a) to 14.2(f) shall apply adapted as necessary to reflect the partial nature of the termination (i.e. applying them on a country-by country basis or Product-by-Product basis), save with respect to Sections 14.2(e) and 14.2(f) to the extent that the same would impact either Party's ongoing performance of the balance of the Agreement.

14.4 No Renewal, Extension or Waiver. Acceptance of any order from, or sale or license of, any Product(s) to Harmony after the notice or effective date of expiration or termination of this Agreement in its entirety shall not be construed as a renewal or extension hereof, or as a waiver of expiration or termination of this Agreement in its entirety.

14.5 Survival. Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except those described in the following Sections: Sections 10.1, 10.2, 10.3, 10.4, 10.8, 11.3(b), 12.6(f), Article 13, Article 14, Article 16, Article 19, Sections 20.2 ,20.3, 20.4, 20.6, 20.7, 20.11, and 20.12.

ARTICLE 15

REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Representations and Warranties of Bioprojet. Bioprojet represents and warrants to Harmony that, as of the Signing Date:

(a) Bioprojet is a corporation duly organized, validly existing and is in good standing under the laws of France, is qualified to do business and is in good standing;

(b) this Agreement and the other Transaction Documents are legal and valid obligations binding upon Bioprojet and enforceable in accordance with their respective terms. The execution, delivery and performance of this Agreement by Bioprojet has been duly authorized by all necessary corporate action and does not and will not in any material respect: (i) to Bioprojet's knowledge, violate any applicable law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or

other agency having jurisdiction over Bioprojet; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding by which Bioprojet is bound;

(c) Bioprojet has the full right and authority to grant the rights and licenses as provided herein;

(d) Bioprojet has not previously granted any right, license or interest in or to the Bioprojet Patents, or any portion thereof, that is in conflict with the rights or licenses granted to Harmony under this Agreement;

(e) there is no action or proceeding pending against Bioprojet that questions in any material respect the validity of this Agreement or any action taken by Bioprojet in connection with the execution of this Agreement;

(f) Bioprojet has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement;

(g) to Bioprojet's actual knowledge after due enquiry of its employees in charge of patent related matters within Bioprojet organization and without a requirement on them to engage external counsel to undertake a FTO analysis, the exploitation of the Product as currently contemplated does not infringe the intellectual property of any Third Party;

(h) to Bioprojet's actual knowledge, there is no infringement by a Third Party of any of the Bioprojet Patents or the Bioprojet Know-How;

(i) to Bioprojet's actual knowledge, none of the issued Bioprojet Patents are invalid or unenforceable; and

(j) Bioprojet is in compliance in all material respects with all, and has not violated in any material respect any, applicable laws with respect to the conduct of its business or the ownership or operation of its properties or assets. Bioprojet is in compliance with, and has conducted and does not have any director, officer, agent, employee, affiliate or other representative who is debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation; excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7 et seq. or any state agency from participation in any federal or state health care program; or otherwise disqualified or restricted by FDA pursuant to 21 C.F.R. § 312.70 or any other regulatory authority.

15.2 Covenants, Representations and Warranties of Harmony. Harmony represents and warrants to Bioprojet that, as of the Signing Date:

(a) Harmony is a limited liability company duly organized, validly existing and is in good standing under the laws of the State of Delaware and is qualified to do business and is in good standing in each other state in which the failure to be so qualified and in good standing would result in a material adverse effect;

(b) this Agreement and the other Transaction Documents are legal and valid obligations binding upon Harmony and enforceable in accordance with their respective terms. The execution, delivery and performance of this Agreement by Harmony has been duly authorized by all necessary limited liability company action and does not and will not in any material respect: (i) require the consent or approval of Harmony's stockholders; (ii) to Harmony's knowledge, violate any applicable law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Bioprojet; nor (iii) conflict with, or constitute a default under, any agreement, instrument or understanding, by which Harmony is bound;

(c) Harmony has the full right and authority to grant the rights and licenses granted herein;

(d) there is no action or proceeding pending against Harmony that questions in any material respect the validity of this Agreement or any action taken by Harmony in connection with the execution of this Agreement;

(e) Harmony has conducted an independent due diligence on the Licensed Assets and the Product(s), with the assistance of its advisers; and

(f) Harmony is in compliance in all material respects with all, and has not violated in any material respect any, applicable laws with respect to the conduct of its business or the ownership or operation of its properties or assets, including the following laws, as applicable: (i) the laws composing the Medicare and Medicaid Programs, including applicable provisions of the Social Security Act (e.g., Civil Monetary Penalties Act, 42 U.S.C. § 1320a-7a, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b), (ii) (x) any other laws prohibiting rebates, kickbacks, fee-splitting or other financial incentives or inducements, including providing products or services below cost for the referral or continuation of business, and (y) the False Claims Act, 31 U.S.C. § 3729 et seq., and (iii) laws enforced by the FDA, including the FDCA and Section 21 of the C.F.R. Harmony is in compliance with, and has conducted and does not have any director, officer, agent, employee, affiliate or other representative who is debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as amended, or any similar state law or regulation; excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7 et seq. or any state agency from participation in any federal or state health care program; or otherwise disqualified or restricted by FDA pursuant to 21 C.F.R. § 312.70 or any other regulatory authority.

15.3 DISCLAIMER. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.

15.4 HSR Filing. Promptly following the Signing Date and no later than fourteen (14) Business Days thereafter, each Party will promptly prepare and submit any necessary filings with the Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a), as amended ("HSR") with respect to this Agreement and the transactions contemplated hereby (collectively, the "HSR Filing") and will use Commercially Reasonable Efforts to obtain expiration of waiting period. Each Party shall (i) promptly notify the other of, and if in writing, furnish the other with copies of any communications from or with the FTC, DOJ or other governmental authority with respect to this Agreement; (ii) permit the other to review and discuss in advance, and consider in good faith the view of the other in connection with, any proposed written or oral communication with the FTC, DOJ or other governmental authority; (iii) not participate in any substantive meeting or have any substantive communication with any governmental authority unless it has given the other party a reasonable opportunity to consult with it in advance and, to the extent permitted by such governmental authority, gives the other the opportunity to attend and participate therein; and (iv) furnish the other party's outside legal counsel with copies of all filings and communications between it and any such governmental authority with respect to the Agreement; provided however, that such material may be redacted as necessary to comply with contractual arrangements, address legal privilege, or comply with applicable law. Each Party shall also furnish the other party's outside legal counsel may reasonably request in connection with its preparation of necessary submissions of information to any such governmental authority. Each Party will be responsible for its own costs; provided that Harmony will pay all filing fee(s) required in the event of an HSR filing or filing for other governmental clearance. Both Parties will use their respective Commercially Reasonable Efforts to cause the clearance to be obtained as quickly as possible. However, neither Party will be required to propose, negotiate, effect or agree to, the sale, divestiture, license or other disposition of any assets or businesses or otherwise take any action that limits the freedom of action with respect to, or its ability to retain any of their respective businesses. In the event that any such approval or expiration of waiting period, as applicable, does not occur within two (2) months from date on which the

HSR filings are made in accordance with this Agreement, either Party may terminate this Agreement under the conditions set forth in Section 13.6 herein.

ARTICLE 16

INDEMNIFICATION

16.1 Indemnification of Bioprojet. Harmony shall indemnify and hold harmless each of Bioprojet, its Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the "Bioprojet Indemnitees"), from and against any and all liabilities, damages, penalties, fines, costs, expenses, claims, actions, suits or proceedings (including, reasonable attorneys' fees and other expenses of litigation) ("Liabilities") incurred by any Bioprojet Indemnitee as a result of: (a) claims, actions, suits or proceedings brought by a Third Party (a "Third Party Claim") arising from or in connection with the use or Commercialization of any Product(s) by or on behalf Harmony, its Affiliates or Sublicensees in the Harmony Territory including, any Product Liability Claim in the Harmony Territory; (b) any breach of any representations, warranties or covenants by Harmony in Article 15 above; (c) any of the representations and warranties given by Harmony in Section 15.2 hereof being untrue or incorrect as of the Effective Date (as if given on the Effective Date) in any material respect as a result of Harmony's actions or inactions during the period beginning on the Signing Date and ending on the Effective Date (including without limitation the items disclosed by Harmony pursuant to clause (A) of Section 17.2(a)(i)), except to the extent such Liabilities fall within the scope of Bioprojet's indemnification obligations set forth in Section 16.2 below or result from the wilful misconduct of a Bioprojet Indemnitee.

16.2 Indemnification of Harmony. Bioprojet shall indemnify and hold harmless each of Harmony, its Affiliates and Sublicensees and the directors, officers and employees of Harmony, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "Harmony Indemnitees"), from and against any and all Liabilities incurred by any Harmony Indemnitee as a result of: (a) a Third Party Claim arising from or in connection with the use or Commercialization of any Product(s) by or on behalf Bioprojet or its licensee in the Bioprojet Territory; (b) any breach of any representations, warranties or covenants by Bioprojet in Article 15 above; (c) any of the representations and warranties given by Bioprojet in Section 15.1 hereof being untrue or incorrect as of the Effective Date (as of given on the Effective Date) in any material respect as a result of Bioprojet's actions or inactions during the period beginning on the Signing Date and ending on the Effective Date (including without limitation the items disclosed by Bioprojet pursuant to clause (A) of Section 17.2(b)(i)); or (d) if the Clearance Date has occurred, any suit, action or other proceeding pending or threatened before any court, governmental body or administrative or other agency (whether filed or arising before, on or after the Clearance Date) wherein an unfavorable injunction, judgment, order, decree, ruling or charge could be reasonably likely to (A) prevent the performance of this Agreement or the consummation of any of the transactions contemplated hereby or declare unlawful any of the transactions contemplated hereby, or (B) cause any of the transactions contemplated by this Agreement to be rescinded following consummation; except to the extent such Liabilities fall within the scope of Harmony's indemnification obligations set forth in Section 16.1 above or result from the wilful misconduct of a Harmony Indemnitee.

16.3 Procedure. A Party that intends to claim indemnification under this Article 16 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Section 16.3 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 16.3, but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Section 16.3. The Indemnitee under this Section 16.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

16.4 Disclaimer of Liability. IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE OR OTHERWISE. NOTWITHSTANDING THE FOREGOING, THIS DISCLAIMER DOES NOT APPLY TO LIABILITY OR DAMAGES (A) RESULTING FROM A BREACH OF CONFIDENTIALITY OBLIGATIONS OF A PARTY UNDER Article 10, OR (B) SUBJECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO SECTIONS 16.1 AND 16.2. For the avoidance of doubt, out-of-pocket costs shall not by their sole nature be deemed indirect or incidental damages and may be regarded as direct damages to the extent directly related to the breach.

16.5 Insurance. Each Party shall secure and maintain in effect, during the Term of this Agreement and for a period of five (5) years thereafter, comprehensive general liability insurance (including product liability insurance), underwritten by a reputable insurance carrier, in a form and having liability limits standard and customary for entities in the pharmaceutical industry based on such Party's activities and indemnification obligations under this Agreement, as applicable. Each Party shall furnish to the other Party, on request, certificates of insurance setting forth the amount of liability insurance and shall provide the other Party at least thirty (30) calendar days' written notice prior to any termination or material reduction to the level of coverage.

ARTICLE 17

CLOSING

17.1 Closing. Subject to the satisfaction of the conditions set forth in Section 17.2 below, the closing (the "Closing") of the transactions contemplated by this Agreement shall take place in no event later than the third business day following the date on which all the conditions set forth in Section 17.2 below shall have been satisfied or waived, unless another time and/or date is agreed to by Harmony and Bioprojet in writing.

17.2 Closing Conditions.

(a) The obligation of Bioprojet to consummate the Closing is subject to the satisfaction of the following conditions on or prior to the Closing:

(i) Harmony shall deliver to Bioprojet a certificate signed by Harmony, dated the Effective Date, stating that (A) except as otherwise disclosed on such certificate, during the period beginning on the Signing Date and ending on the Effective Date Harmony has taken no action, or failed to take any action, that resulted in the representations and warranties given by Harmony in Section 15.2 hereof being untrue or incorrect as of the Effective Date and (B) except as otherwise disclosed on such certificate, as of the Effective Date, Harmony does not have actual knowledge that any of the representations and warranties given by Harmony in Section 15.2 are untrue or incorrect as of the Effective Date; and

(ii) the Clearance Date shall have occurred.

(b) The obligation of Harmony to consummate the Closing is subject to the satisfaction of the following conditions on or prior to the Closing:

(i) Bioprojet shall deliver to Harmony a certificate signed by Bioprojet, dated the Effective Date, stating that (A) except as otherwise disclosed on such certificate, during the period beginning on the Signing Date and ending on the Effective Date Bioprojet has taken no action, or failed to take any action, that resulted in the representations and warranties given by Bioprojet in Section 15.1 hereof being untrue or incorrect as of the Effective Date and (B) except as otherwise disclosed on such certificate, as of the Effective Date, Bioprojet does not have actual knowledge that any of the

representations and warranties given by Bioprojet in Section 15.1 are untrue or incorrect as of the Effective Date; and

(ii) the Clearance Date shall have occurred.

ARTICLE 18

EXCLUSIVITY

18.1 Exclusivity. During the period beginning on the Signing Date and ending upon the Effective Date or termination of this Agreement, if later, in accordance with its terms, Bioprojet shall not engage in discussions or negotiations (or provide information to) any Third Party (regardless of whether such Third Party has been contacted by Bioprojet or its representatives before and whether such Third Party has previously engaged in discussions or negotiations with Bioprojet or its representatives), solicit offers or enter into any binding agreement or non-binding term sheet with any Third Party whatsoever regarding the Development, Manufacture Commercialization of the Product(s) in the Harmony Territory that conflicts with this Agreement or is detrimental to Harmony's interests therein.

ARTICLE 19

DISPUTE RESOLUTION

19.1 Arbitration.

(a) In the event a dispute arises and the Parties are unable, for any reason, to resolve it through the JSC (each, a "Dispute"), either Party may submit such Dispute to arbitration for final resolution by arbitration request under the Rules of Arbitration of the International Chamber of Commerce (the "Rules") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "Arbitration"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language. The place of arbitration shall be Paris, France and the language used in the arbitral proceedings shall be English. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators.

(b) Confidentiality. Except to the limited extent necessary to comply with applicable law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

(c) Communications with Internal Counsel. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of applicable law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

ARTICLE 20

GENERAL PROVISIONS

20.1 Force Majeure. If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of such Party (including, fire, flood, earthquake, tsunami, embargo, power shortage or failure, acts of war, insurrection, pandemic or epidemic, riot, terrorism, strike, lockout or other labor disturbance, acts of God or any acts, omissions or delays in acting of the other Party), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

20.2 Governing Law. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement and resolution of all Disputes and any remedies relating thereto, shall be governed by, and construed and enforced in accordance with, the laws of England and Wales, without reference to conflict of law principles.

20.3 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

20.4 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

20.5 Severability. In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Agreement upon sixty (60) days' prior written notice to the asserting Party, unless such assertion is eliminated and the effect of such assertion cured within such sixty (60) day period. Any termination in accordance with the foregoing shall be deemed a termination under Section 13.2 by reason of a breach by the Party who made such assertion. Further, if any statute or statutory provision is enacted, re-enacted, amended or extended in a way that makes it no longer commercially reasonable to pursue the Development or Commercialization contemplated by this Agreement the Parties consider the situation in good faith and shall use Commercially Reasonable Efforts, including amendment or modification of this Agreement, to try to achieve the same economic result through an alternative arrangement that most nearly reflects the original intent of the Parties.

20.6 Entire Agreement; Amendments. This Agreement (including the Exhibits attached hereto), together with the Transaction Documents (when executed), constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

20.7 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be in writing in the English

language, and (a) delivered personally, (b) sent by express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission or facsimile (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

To Bioprojet:	To Harmony:
Bioprojet Société Civile de Recherche 30, rue des Francs-Bourgeois, 75003 Paris, France Attention: [***]	Harmony Biosciences, LLC 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania, USA Attention:legal@harmonybiosciences.com
With a copy to:	With a copy to:
McDermott Will & Emery AARPI 23 rue de l'Université 75007 Paris, France Attention: Emmanuelle Trombe [***]	Hogan Lovells US LLP 100 International Drive Baltimore, Maryland 21208 USA Attention: William Intner [***]

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

20.8 Assignment. This Agreement shall not be assignable by either Party to any Third Party hereto without the written consent of the other Party hereto. Either Party shall have the right to assign this Agreement to an Affiliate, with the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed); provided that the assigning Party guarantees the performance of this Agreement by such Affiliate and such Affiliate agrees in a writing delivered to the non-assigning Party to assume all of the rights and obligations of the assigning Party under this Agreement; and further provided that if the non-assigning Party reasonably believes such assignment could result in material adverse tax consequences to the non-assigning Party, the non-assigning Party shall have no obligation to consent to the proposed assignment. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 20.8 shall be null and void.

20.9 No Partnership or Joint Venture. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Harmony and Bioprojet. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

20.10 Third Party Rights. Except as expressly stated in this Agreement, a person who is not a Party to this Agreement may not enforce any of its terms under the Contracts (Rights of Third Parties) Act 1999.

20.11 Anti-Corruption Laws and Sanctions and Export Controls.

(a) Sanctions and Export Controls. Neither Party shall be required to take or refrain from taking any action that would be prohibited or penalisable under any Sanctions and Export Controls.

(b) Anti-Corruption Laws. Each Party shall fully comply, and shall procure that its Affiliates, Approved Contractors and Sub-Licensees and its and their respective directors, officers, employees, contractors, agents and authorised representatives, comply with Anti-Corruption Laws.

20.12 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement.

20.13 Counterparts; Other Matters. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this License and Commercialization Agreement as of the date first set forth above.

Bioprojet Société Civile de Recherche

BY: /s/ Jeanne-Marie Lecomte

NAME: Jeanne-Marie Lecomte

TITLE: Chairman

Harmony Biosciences, LLC

BY: /s/ John Jacobs

NAME: John Jacobs

TITLE: President & CEO

EXHIBIT 1.11

Bioprojet Patents

Territory	Filing date	Filing number	Title	Status
[***]	[***]	[***]	[***]	[***]

EXHIBIT 3.1(a)

Initial Development Plan

[***]

AMENDMENT NO. 1 TO CREDIT AGREEMENT

THIS AMENDMENT NO. 1 TO CREDIT AGREEMENT, dated as of August 2, 2022 (this "**Amendment**"), is by and among HARMONY BIOSCIENCES HOLDINGS, INC., a Delaware corporation (the "**Borrower**"), its wholly owned subsidiary, HARMONY BIOSCIENCES, LLC, a Delaware limited liability company ("**Harmony**"), as the sole initial Guarantor and the Lenders (as defined in the Credit Agreement referred to below).

WITNESSETH

WHEREAS, the Borrower, Harmony, the Lenders and WILMINGTON TRUST, NATIONAL ASSOCIATION, as Administrative Agent (as defined therein) are party to that certain Credit Agreement, dated as of August 9, 2021 (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "**Credit Agreement**", the Credit Agreement as amended by this Amendment, the "**Amended Document**"); and

WHEREAS, the parties have agreed to amend certain provisions of the Credit Agreement as hereinafter provided, in each case, subject to the satisfaction of the conditions precedent to effectiveness set forth in Section 3 hereof.

NOW THEREFORE, in consideration of the foregoing and the mutual agreements and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) Terms Defined in the Credit Agreement. All capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings assigned to them in the Credit Agreement.

(b) Interpretation. The rules of interpretation set forth in Section 1.02 of the Credit Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments.

(a) The following definitions shall be added to Section 1.01 of the Credit Agreement, in their respective appropriate alphabetical locations:

(i) "*First Amendment*" means that certain Amendment No. 1 to Credit Agreement, dated as of August 2, 2022, by and among the Borrower, Harmony, the Administrative Agent and the Lenders.

(ii) "*First Amendment Effective Date*" has the meaning specified in the First Amendment, which date is August 2, 2022."

(iii) "*Ticking Fee*" has the meaning specified therefor in Section 2.07(c).

(iv) "*Ticking Fee Accrual Period*" has the meaning specified therefor in Section 2.07(c).

(b) The definition of "Outside Date" in Section 1.01 of the Credit Agreement is hereby amended and restated in its entirety as follows:

"*Outside Date*" means August 9, 2023 or such later date as may be agreed by the Lender Representative and the Borrower in their sole discretion and notified by the Borrower or the Lender Representative to the Administrative Agent in writing."

(c) Section 2.07 of the Credit Agreement is hereby amended by adding the following new clause (c) at the end thereof:

"(c) Ticking Fee. From and after August 10, 2022 and until the last day of the Delayed Draw Availability Period (the "**Ticking Fee Accrual Period**"), the Borrower shall pay to the Administrative Agent for the account of each Lender with a Delayed Draw Commitment, in accordance with its pro rata share, a ticking fee (the "**Ticking Fee**"), which shall accrue daily on each day during the Ticking Fee Accrual Period at the rate per annum of 1.00% on the aggregate undrawn Delayed Draw Commitments of all Lenders. Accrued and unpaid Ticking Fees shall be payable upon each Borrowing of the Delayed Draw Loans and upon the expiration of the Delayed Draw Availability Period."

SECTION 3 Conditions. The effectiveness of this Amendment is subject to the satisfaction of the following conditions precedent (the date on which the following conditions are satisfied or waived, the "**First Amendment Effective Date**"):

(a) the Borrower, Harmony, the Lenders and the Administrative Agent shall have executed and delivered this Amendment; and

(b) no Default exists upon, or would immediately result from, giving effect to this Amendment.

SECTION 4 Miscellaneous.

(a) Amended Document Otherwise Not Affected; No Waiver. (i) Nothing contained herein shall be deemed to constitute a waiver of any existing or future Default or Event of Default or compliance with any term or condition contained in the Amended Document or any of the other Loan Documents or constitute a course of conduct or dealing among the parties and (ii) the Lenders and the Administrative Agent reserve all rights, privileges and remedies under the Amended Document and the other Loan Documents.

(b) Loan Document Pursuant to Credit Agreement. This Amendment is a Loan Document executed pursuant to the Credit Agreement and each other Loan Document and shall (unless otherwise expressly indicated therein) be construed, administered and applied in accordance with all of the terms and provisions of the Amended Document, as amended hereby.

(c) Successors and Assigns. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

(d) Governing Law. **THIS AMENDMENT, AND ALL MATTERS ARISING OUT OF OR RELATING TO THIS WAIVER AND AMENDMENT, SHALL BE GOVERNED BY THE LAWS OF THE STATE OF NEW YORK.**

(e) Counterparts. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Delivery of an executed signature page of this Amendment by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof.

(f) Full Force and Effect; Limited Consent. The modifications set forth in this Amendment shall be limited precisely as provided for herein to the provisions expressly modified hereby and shall not be deemed to be a consent to, waiver of, or modification of any other term or provision of the Amended Document or any other Loan Document or of any transaction or further or future action on the part of the Borrower which would require the consent of the Administrative Agent or Lenders under the Amended Document or any of the Loan Documents.

(g) Release. Each of the Loan Parties, for itself and its successors, assigns, parents, subsidiaries, affiliates, predecessors, employees, agents, heirs and executors, as applicable, hereby fully and unconditionally releases each of the Lenders, and their respective directors, officers, employees, subsidiaries, affiliates, attorneys, agents, representatives, successors and assigns (collectively, the "**Released Parties**") from any and all claims, causes of action, costs or demands of whatever kind or nature, whether known or unknown, liquidated or unliquidated, fixed or contingent, asserted or unasserted, foreseen or unforeseen, or matured or unmatured, which any Loan Party may have had against the Released Parties by reason of any act or omission on the part of the Released Parties occurring prior to the date hereof, in each case regarding or relating to the Amended Document or the other Loan Documents (collectively, the "**Released Matters**"); *provided*, that Released Matters shall not include any claims, causes of action, costs or demands of whatever kind or nature, whether known or unknown, liquidated or unliquidated, fixed or contingent, asserted or unasserted, foreseen or unforeseen, or matured or unmatured, resulting from the gross negligence or willful misconduct of the Released Parties, as determined by a court of competent jurisdiction in a final and non-appealable judgment or order. Each of the Loan Parties represents and warrants that (i) it has no knowledge of any such claims by it against the Released Parties and (ii) that the foregoing constitutes a full and complete release of all such claims.

[Remainder of page intentionally left blank; signature pages follow]

BORROWER **HARMONY BIOSCIENCES HOLDINGS, INC.**

By: DocuSigned by: John Jacobs 55262AC7BDA44FA...

Name: John C. Jacobs

Title: President and Chief Executive Officer

GUARANTOR **HARMONY BIOSCIENCES, LLC**

By: DocuSigned by: John Jacobs 55262AC7BDA44FA...

Name: John C. Jacobs

Title: President and Chief Executive Officer

LENDERS **ALOE SUB LLC**,
as a Lender

By: Aloe Top Sub LLC, its sole member
By: Aloe Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

ALPACA SUB LLC,
as a Lender

By: Alpaca Top Sub LLC, its sole member
By: Alpaca Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

BEGONIA SUB LLC,
as a Lender

By: Begonia Top Sub LLC, its sole member
By: Begonia Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

CACTUS SUB LLC,
as a Lender

By: Cactus Top Sub LLC, its sole member
By: Cactus Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

FERN SUB LLC,
as a Lender

By: Fern Top Sub LLC, its sole member
By: Fern Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

GRASS SUB LLC,
as a Lender

By: Grass Top Sub LLC, its sole member
By: Grass Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

HOLLY SUB LLC,
as a Lender

By: Holly Top Sub LLC, its sole member
By: Holly Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

Title: Authorized Signatory

IVY SUB LLC,
as a Lender

By: Ivy Top Sub LLC, its sole member
By: Ivy Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

MOSS SUB LLC,
as a Lender

By: Moss Top Sub LLC, its sole member
By: Moss Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

POTHOS SUB LLC,
as a Lender

By: Pothos Top Sub LLC, its sole member
By: Pothos Topco LP, its sole member
By: BXC Azul Associates LLC, its general partner

By: 
Name: Marisa Beeney
Title: Authorized Signatory

GSO CREDIT ALPHA FUND II-C AIV-1, LP,
as a Lender

By: GSO Credit Alpha Associates II LP, its General Partner
By: GSO Credit Alpha Associates II (Delaware) LLC, its General Partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

GSO CREDIT ALPHA FUND II-C AIV-4, LP,
as a Lender

By: GSO Credit Alpha Associates II LP, its General Partner
By: GSO Credit Alpha Associates II (Delaware) LLC, its General Partner

By: 

Name: Marisa Beeney
Title: Authorized Signatory

Title: Authorized Signatory

LENDER **BXLS YIELD – DUET (DE) L.P.**,

as a Lender

By: Blackstone Life Sciences Advisors L.L.C. on behalf of BXLS Yield – Duet (DE) L.P

By: Robert W. Liptak

Name: Robert Liptak

Title: Chief Operating Officer

Exhibit 31.1

Certification of Principal Executive Officer

I, John C. Jacobs, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2022

By: /s/ John C. Jacobs

John C. Jacobs

Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Sandip Kapadia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2022

By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

Certification of Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of The Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2022

By: /s/ John C. Jacobs
John C. Jacobs
Chief Executive Officer, President and Director
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as a part of the Report or on a separate disclosure document.

Exhibit 32.2

Certification of Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of The Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2022

By: /s/ Sandip Kapadia

Sandip Kapadia
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as a part of the Report or on a separate disclosure document.