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 March 31, 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 April 29, 2022, there were 59,048,228 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)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 224,499	$ 234,309
Trade receivables, net	38,133	34,843
Inventory, net	4,597	4,432
Prepaid expenses	9,618	7,637
Other current assets	3,410	3,218
Total current assets	280,257	284,439
NONCURRENT ASSETS:		
Property and equipment, net	748	820
Restricted cash	750	750
Intangible assets, net	178,837	143,919
Other noncurrent assets	3,413	3,515
Total noncurrent assets	183,748	149,004
TOTAL ASSETS	$ 464,005	$ 433,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,904	$ 1,001
Accrued compensation	4,976	9,165
Accrued expenses	39,380	40,249
Current portion of long term debt	2,000	2,000
Other current liabilities	3,268	1,360
Total current liabilities	56,528	53,775
NONCURRENT LIABILITIES:		
Long term debt, net	189,896	189,984
Other noncurrent liabilities	3,078	3,177
Total noncurrent liabilities	192,974	193,161
TOTAL LIABILITIES	249,502	246,936
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2022 and December 31, 2021, respectively; 59,030,148 shares and 58,825,769 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	1	1
Additional paid in capital	646,615	640,104
Accumulated deficit	(432,113)	(453,598)
TOTAL STOCKHOLDERS' EQUITY	214,503	186,507
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 464,005	$ 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 March 31,	
	2022	2021
Net product revenues	$ 85,313	$ 59,674
Cost of product sold	14,716	10,409
Gross profit	70,597	49,265
Operating expenses:		
Research and development	7,578	4,679
Sales and marketing	17,583	15,506
General and administrative	17,880	14,547
Total operating expenses	43,041	34,732
Operating income	27,556	14,533
Other expense, net	(2)	(20)
Interest expense, net	(4,169)	(7,127)
Income before income taxes	23,385	7,386
Income tax expense	(1,900)	—
Net income and comprehensive income	$ 21,485	$ 7,386
EARNINGS PER SHARE:		
Basic	$ 0.36	$ 0.13
Diluted	$ 0.35	$ 0.13
Weighted average number of shares of common stock - basic	58,908,526	56,891,451
Weighted average number of shares of common stock - diluted	60,586,875	58,805,285

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 deficit	Total stockholders' equity
	Shares	Amount			
Balance as of December 31, 2021	58,825,769	$ 1	$ 640,104	$ (453,598)	$ 186,507
Net income	—	—	—	21,485	21,485
Exercise of options	204,379	—	1,883	—	1,883
Stock-based compensation	—	—	4,628	—	4,628
Balance as of March 31, 2022	59,030,148	$ 1	$ 646,615	$ (432,113)	$ 214,503

	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	—	—	—	7,386	7,386
Exercise of stock options	1,837	—	12	—	12
Stock-based compensation	—	—	3,301	—	3,301
Balance as of March 31, 2021	56,892,406	$ 1	$ 588,687	$ (480,809)	$ 107,879

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)

	Three Months Ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 21,485	$ 7,386
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	117	100
Intangible amortization	5,082	4,579
Stock-based and employee stock purchase compensation expense	4,628	3,301
Stock appreciation rights market adjustment	268	(50)
Debt issuance costs amortization	412	664
Non-cash lease expense	385	264
Change in operating assets and liabilities:		
Trade receivables	(3,290)	(1,439)
Inventory	(165)	(582)
Prepaid expenses and other assets	(2,235)	(296)
Trade payables	5,903	1,835
Accrued expenses and other current liabilities	(3,586)	(3,200)
Other non-current liabilities	(152)	(32)
Net cash provided by operating activities	28,852	12,530
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(45)	(4)
Milestone payments	(40,000)	(100,000)
Net cash used in investing activities	(40,045)	(100,004)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal repayment of long term debt	(500)	—
Proceeds from exercised options	1,883	12
Net cash provided by financing activities	1,383	12
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(9,810)	(87,462)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	235,059	229,381
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 225,249	$ 141,919
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 3,829	$ 6,510

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. (the "Company") was founded in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and the Company converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017. In February 2020, the Company changed its name to Harmony Biosciences Holdings, Inc. The Company is a holding company and has no operations. The Company's operations are conducted in its wholly owned subsidiary, Harmony Biosciences, LLC ("Harmony"), which was formed in May 2017. The Company is a commercial-stage, rare disease pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare 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 an IPO 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 has an accumulated deficit of $432,113 and $453,598, as of March 31, 2022 and December 31, 2021, respectively. As of March 31, 2022, the Company had cash and cash equivalents of $224,499.

The Company believes that its existing cash and cash equivalents on hand as of March 31, 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 March 31, 2022, the unaudited condensed consolidated statements of cash flows for the three months ended March 31, 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 months ended March 31, 2022 and 2021, are unaudited. The balance sheet as of March 31, 2021 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 March 31, 2022, and the results of its operations and its cash flows for the three months ended March 31, 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 note disclosures of the Company 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 9 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. Uncertainties related to the magnitude and duration of COVID-19, the extent to which it will impact our estimated 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 these estimates, including the carrying amounts of long-lived assets, and the intangible asset. Actual results may differ significantly from our estimates, including as a result of COVID-19.

Fair Value of Financial Instruments

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, in general, to measure non-financial assets and liabilities at fair value on a nonrecurring basis. The instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (such as evidence of impairment), which, if material, are disclosed in the accompanying footnotes.

The Company measures certain assets and liabilities at fair value in accordance with ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy that serves to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3—Valuations based on unobservable inputs and models that are supported by little or no market activity.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents 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. 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	
	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 224,499	$ 234,309
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 225,249	$ 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.

Concentrations of Risk

Substantially all of the Company's cash and money market funds are held with a single financial institution. Due to its size, the Company believes this financial institution represents minimal credit risk. Deposits 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 monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. 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. As of March 31, 2022, three customers accounted for 100% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 38% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 32% of gross accounts receivable; and PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 30% 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 three months ended March 31, 2022, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 38% of gross product revenues; Pantherx accounted for 32% of gross product revenues; and Accredo accounted for 30% of gross product revenues. For the three months ended March 31, 2021 three customers accounted for 100% of gross product revenues; Pantherx accounted for 38% of gross product revenues CVS Caremark accounted for 35% of gross product revenues; and Accredo accounted for 27% of gross product revenues.

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

Agreement Related to Intellectual Property

In August 2021, the Company entered into an asset purchase agreement with ConSynance Therapeutics, Inc. 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 agreement, 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 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.

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. INVENTORY

Inventory, net consisted of the following:

	As of	
	March 31, 2022	December 31, 2021
Raw materials	$ 810	$ 986
Work in process	2,362	1,787
Finished goods	1,874	2,108
Inventory, gross	5,046	4,881
Reserve for excess inventory	(449)	(449)
Total inventory, net	$ 4,597	$ 4,432

5. 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 License Agreement (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 March 31, 2022 the remaining useful life was 7.5 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 License Agreement 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 March 31, 2022 the remaining useful life was 7.5 years.

In February 2022, the Company attained $500,000 in aggregate net sales of WAKIX in the United States. This event triggered a final $40,000 payment under the provisions of the License Agreement 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 March 31, 2022 the remaining useful life was 7.5 years.

Amortization expense was $5,082 and $4,579 for the three months ended March 31, 2022 and 2021, respectively, and is recorded in general and administrative expenses on the unaudited condensed consolidated statements of operations and comprehensive income (loss).

The Company expects the future annual amortization expense for the unamortized intangible assets to be as follows:

Years ending December 31,	
2022 (Excluding the three months ended March 31, 2022)	$ 17,884
2023	23,845
2024	23,845
2025	23,845
2026	23,845
Thereafter	65,573
Total	$ 178,837

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

	As of	
	March 31, 2022	**December 31, 2021**
Gross Carrying Amount	$ 215,000	$ 175,000
Accumulated Amortization	(36,163)	(31,081)
Net Book Value	$ 178,837	$ 143,919

6. LICENSE AGREEMENT

In July 2017, Harmony entered into the License Agreement ("the License Agreement") 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 License Agreement 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 $13,672 and $9,547 for the three months ended March 31, 2022 and 2021, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of March 31, 2022 and December 31, 2021, the Company had accrued $13,650 and $16,396, respectively, for sales-based, trademark and tiered royalties.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	March 31, 2022	December 31, 2021
Royalties due to third parties	13,650	16,396
Rebates and other sales deductions	19,479	17,141
Interest	2,120	2,125
Selling and marketing	1,256	1,983
Research and development	423	658
Professional fees, consulting, and other services	1,554	1,645
Other expenses	898	301
	$ 39,380	$ 40,249

8. DEBT

Credit Agreements

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 will be available to draw down through August 9, 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 Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%.

The net cash received related to 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 will be 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 March 31, 2022 was $169,966.

Long-term debt, net consists of the following:

	March 31, 2022	December 31, 2021
Liability component - principal	$ 199,000	$ 199,500
Unamortized debt discount associated with debt financing costs	(7,104)	(7,516)
Liability component - net carrying value	191,896	191,984
Less current portion	(2,000)	(2,000)
Long term debt, net	$ 189,896	$ 189,984

Future minimum payments relating to long term debt, net as of March 31, 2022 for the periods indicated below consists of the following:

Years ending December 31,	
2022 (Excluding the three months ended March 31, 2022)	$ 1,500
2023	2,000
2024	20,000
2025	20,000
2026	155,500
Thereafter	—
Total	$ 199,000

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

	Three Months Ended March 31,	
	2022	2021
Interest on principal balance	$ 3,824	$ 6,510
Amortization of deferred financing costs	412	664
Total term loan interest expense	$ 4,236	$ 7,174

9. 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 $385 and $264 for the three months ended March 31, 2022 and 2021, respectively.

As of March 31, 2022, the weighted-average remaining lease term for operating leases was 2.3 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	March 31, 2022	December 31, 2021
Assets			
Operating lease right-of-use assets	Other noncurrent assets	$ 3,134	$ 3,298
Liabilities			
Operating lease liability, current portion	Other current liabilities	$ 1,535	$ 1,527
Operating lease liability, long-term	Other long-term liabilities	2,018	2,233
Total operating lease liabilities		$ 3,553	$ 3,760

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

	March 31, 2022	March 31, 2021
Operating cash flows from operating leases	$ 434	$ 267
Right of use assets obtained in exchange for operating lease obligations (1)	$ 234	$ 1,958

(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 March 31, 2022 consisted of the following:

Years ending December 31,	
2022 (Excluding the three months ended March 31, 2022)	$ 1,240
2023	1,591
2024	866
2025	6
2026	—
Thereafter	—
Total lease payments	3,703
Less: imputed interest	(150)
Total lease liabilities	$ 3,553

10. 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 March 31, 2022, there were no claims or suits outstanding.

11. 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.

12. 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 March 31, 2022, there were 5,089,156 shares of common stock reserved 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 three months ended March 31, 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	1,377,307	$ 49.33	
Awards exercised	(205,432)	$ 9.35	
Awards forfeited	(63,665)	$ 27.97	
Awards outstanding—March 31, 2022	6,824,807	$ 28.29	8.33

Stock Appreciation Rights

The following table summarizes SARs activity for the three months ended March 31, 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—March 31, 2022	43,208	$ 9.38	7.08

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 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—March 31, 2022	60,000	$ 29.03	8.99

As of March 31, 2022 and December 31, 2021, stock awards issued under the 2017 and 2020 Plans of 1,225,948 and 1,285,432 common shares, respectively, were vested.

Value of Stock Options and SARs

The Company has valued awards for each of the plans included herein 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. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

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

	As of	
	March 31, 2022	December 31, 2021
Dividend yield	0.00 %	0.00 %
Expected volatility	72.60-72.70 %	60.00 %
Risk-free interest rate	1.99 - 2.37 %	0.66 - 1.44 %
Expected term (years)	3.9 - 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 $16.94 and $12.82 on March 31, 2022 and December 31, 2021, respectively.

Stock-Based Compensation

Stock-based compensation expense, net for the three months ended March 31, 2022 and 2021, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income in the following line items:

	Three Months Ended March 31,	
	2022	2021
Research and development expense	$ 518	$ 420
Sales and marketing expense	976	620
General and administrative expense	3,402	2,211
	$ 4,896	$ 3,251

Options and RSUs issued under the 2017 Plan and 2020 Plan are included in stockholder's equity, and SARs are included in other non-current liabilities, in the Company's unaudited condensed consolidated balance sheet. As of March 31, 2022, the total unrecognized stock-based compensation expense related to Options and RSUs was $95,566. Such amount will be recognized in the Company's consolidated statement of operations over a weighted average period of 3.5 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 the three months ended March 31, 2022, there were no shares issued under the ESPP. The discount on the ESPP for the three months ended March 31, 2022 was $94 and is recorded within stock-based compensation expense.

13. EARNINGS PER SHARE

The Company has reported net income for both the three months ended March 31, 2022 and 2021. 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 attributable to common stockholders, the potential dilutive effects of stock options, stock appreciation rights, restricted stock units and warrants. In addition, the Company analyzes the potential dilutive effects of the outstanding convertible preferred stock under the 'if-converted' method when calculating diluted earnings per share, in which it is assumed that the outstanding convertible preferred stock converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (treasury stock or 'if converted') as its diluted net income per share during the period.

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

	Three Months Ended March 31,	
	2022	2021
Numerator		
Net income	$ 21,485	$ 7,386
Denominator		
Net income per common share - basic	$ 0.36	$ 0.13
Net income per common share - diluted	$ 0.35	$ 0.13
Weighted average number of shares of common stock - basic	58,908,526	56,891,451
Weighted average number of shares of common stock - diluted	60,586,875	58,805,285

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

	Three Months Ended March 31,	
	2022	2021
Stock options, SARs, and RSUs to purchase common stock	1,678,349	1,691,882
Warrants	—	221,953
Total	1,678,349	1,913,835

Potential common shares issuable upon exercise of stock options, and exercise of warrants that were excluded from the computation of diluted weighted-average shares outstanding as well as the warrant fair value adjustments excluded from the numerator are as follows:

	Three Months Ended March 31,	
	2022	2021
Stock options, SARs, and RSUs to purchase common stock	5,249,666	4,683,323
Warrants	—	188,286
Total	5,249,666	4,871,609

14. 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 March 31, 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 March 31, 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 agreement 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 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, rare disease pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare 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").

We are currently considering label expansion for WAKIX in narcolepsy in pediatric patients and have engaged with the FDA in pursuit of pediatric exclusivity. Our strategic partner, Bioprojet has evaluated in pediatric patients with narcolepsy and completed a Phase 3 trial. We are working with Bioprojet to assess the data from the Phase 3 trial to inform how best to advance the pediatric narcolepsy program. We believe that our strategic decision to assess this data is the most prudent and thoughtful path forward for pediatric narcolepsy from a development and financial perspective. In the meantime, we continue to evaluate regulatory strategies with regard to obtaining pediatric exclusivity.

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. Beyond narcolepsy, we are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome ("PWS") and myotonic dystrophy, otherwise known as dystrophia myotonica ("DM"). In December 2020, we initiated a Phase 2 proof-of-concept clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS and anticipate topline results from this trial in the second half of 2022. In June 2021, we initiated a Phase 2 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. In addition to these clinical programs, we have initiated a Phase 3 registrational trial to evaluate the efficacy and safety of pitolisant in adult patients with idiopathic hypersomnia ("IH").

We also seek to expand our pipeline through the acquisition of additional assets that focus on addressing the unmet needs of patients with rare neurological diseases and 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 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 are currently on track to begin 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 later in 2022.

Pitolisant was developed by Bioprojet and approved by the European Medicines Agency ("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 "Bioprojet License Agreement") 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 March 31, 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 March 31, 2022 was approximately 3,900. Additionally, as of March 31, 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 second quarter of 2023, 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 may not be directly 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 each patient 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 began to and cases began to decline, all of our have returned to in-person operations with flexibility as needed, which we feel 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 our 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

Total revenue consists of net sales of WAKIX. Net sales represent the gross sales of WAKIX less provisions for product 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 product 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. We began capitalizing inventory upon FDA approval of WAKIX. 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 our product is three years from date of manufacture, with the earliest expiration of current inventory expected to be April 2023. We regularly review our inventory levels and expect write-offs from time to time. We will continue to assess our inventory levels in future periods as demand for WAKIX and the rate of inventory turnover evolves.

Research and Development Expenses

Our research and development expenses generally include development programs for potential new indications for pitolisant in patients with PWS, DM and IH. We also have 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 PWS, DM and IH 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 labeling 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 have primarily related to the market development and commercialization activities of WAKIX for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy. Market development and commercial activities account for a significant portion of the overall company operating expenses and are expensed as they are incurred. We expect our sales and marketing expenses to increase in the near- and mid-term to support our 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, these 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, consulting fees and travel expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our personnel in executive, legal, finance and accounting, human resources, 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 months ended March 31, 2022, we paid $0.1 million pursuant to this agreement.

Interest Expense, Net

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

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 March 31,	
	2022	2021
	(In thousands)	
Net product revenue	$ 85,313	$ 59,674
Cost of product sales	14,716	10,409
Gross profit	70,597	49,265
Operating expenses:		
Research and development	7,578	4,679
Sales and marketing	17,583	15,506
General and administrative	17,880	14,547
Total operating expenses	43,041	34,732
Operating income	27,556	14,533
Other expense, net	(2)	(20)
Interest expense, net	(4,169)	(7,127)
Net income before provision for income taxes	23,385	7,386
Income tax expense	(1,900)	—
Net income	$ 21,485	$ 7,386

Net Product Revenue

Net product revenue increased by $25.6 million, or 43.0%, for the three months ended March 31, 2022 compared to the same period in 2021. The increase was due to the growth in the average number of patients on WAKIX.

Cost of Product Sales

Cost of product sales increased by $4.3 million, or 41.4%, for the three months ended March 31, 2022 compared to the same period in 2021. The increase 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 $2.9 million, or 62.0%, for the three months ended March 31, 2022 as compared to the same period in 2021. The increase was due to clinical development work associated with PWS, DM and IH and an increase to stock compensation associated with new awards.

Sales and Marketing Expenses

Sales and marketing expenses increased by $2.1 million, or 13.4% for the three months ended March 31, 2022 as compared to the same period in 2021. The increase was primarily due to patient engagement and marketing activities driven by our commercialization of WAKIX and an increase to stock-compensation expense associated with new awards.

General and Administrative Expenses

General and administrative expenses increased by $3.3 million, or 22.9% for the three months ended March 31, 2022 as compared to the same period in 2021. This increase was primarily due to an increase to stock compensation associated with new awards and an increase in intangible asset amortization as a result

of the $40.0 million milestone payment upon attaining $500.0 million in aggregate net sales of WAKIX in the United States.

Interest Expense, Net

Interest expense decreased by $3.0 million, or 41.5%, for the three months ended March 31, 2022 as compared to the same period in 2021 primarily due to lower interest rates as a result of entering into the Blackstone Credit Agreement in August 2021, partially offset by an increase in amortization of deferred financing costs.

Income Taxes

For interim periods, we estimate the annual effective income tax rate and apply the estimated rate to the year-to-date income or loss before income taxes. The effective income tax rate was 8.1% and 0.0% for the three months ended March 31, 2022 and 2021, respectively. Currently, we have recorded a full valuation allowance against our net deferred tax assets, primarily related to federal and state net operating losses.

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. On August 21, 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 March 31, 2022, we had cash, cash equivalents and restricted cash of $225.2 million and accumulated deficit of $432.1 million. As of March 31, 2022, we had outstanding debt of $199.0 million.

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), and existing cash and cash equivalents 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, 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 $200.0 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 will be available to draw down through August 9, 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 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. The Company is in compliance with all covenants as of March 31, 2022.

Agreement Related to Intellectual Property

In August 2021, the Company 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, the Company 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.

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 Bioprojet License Agreement. 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 aggregate net sales in the United States.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
Selected cash flow data	(In thousands)	
Cash provided by (used in):		
Operating activities	$ 28,852	$ 12,530
Investing activities	(40,045)	(100,004)
Financing activities	1,383	12

Operating Activities

Net cash provided by operating activities for the three months ended March 31, 2022 consisted of our net income of $21.5 million adjusted for non-cash items of $5.2 million related to intangible amortization and depreciation and $4.9 million related to stock-based compensation expense. Net working capital excluding cash decreased by $3.5 million.

Net cash provided by operating activities for the three months ended March 31, 2021 consisted of our net income of $7.4 million adjusted for non-cash items of $4.7 million related to intangible amortization and depreciation and $3.3 million related to stock-based compensation expense. Net working capital excluding cash decreased by $3.7 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was $40.0 million, which was primarily attributable to a final $40.0 million milestone payment associated with the Bioprojet License Agreement. Net cash used in investing activities for the three months ended March 31, 2021 was $100.0 million, which was primarily attributable to the $100.0 million milestone payment associated with the Bioprojet License Agreement.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 was $1.4 million, which primarily consisted of $1.9 million in proceeds from exercised options offset by $0.5 million in principal payments associated with the Blackstone Credit Agreement. There were no significant financing activities for the three months ended March 31, 2021.

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. As of March 31, 2022, our cash and cash equivalents consisted of cash and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of March 31 2022, we had $199.0 million in borrowings outstanding. The term loan bears interest at an interest rate equal to LIBOR (subject to a 1.00% floor) plus 6.50%. Based on the $199.0 million of principal outstanding as of March 31, 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 months ended March 31, 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 March 31, 2022. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 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 March 31, 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.

None.

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*	Amendment to the Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan.			
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 March 31, 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.

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:	May 3, 2022

By:	/s/ Sandip Kapadia
Name:	Sandip Kapadia
Title:	Chief Financial Officer (principal financial officer)
Date:	May 3, 2022

AMENDMENT TO THE

HARMONY BIOSCIENCES HOLDINGS, INC.

2020 INCENTIVE AWARD PLAN

THIS AMENDMENT (the "***Amendment***") to the Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan (the "***Plan***"), is made and adopted by the Board of Directors (the "***Board***") of Harmony Biosciences Holdings, Inc. (the "***Company***"), effective as of March 24, 2022 (the "***Effective Date***"). All capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Plan (as defined below).

RECITALS

WHEREAS, the Company maintains the Plan, as may be amended from time to time;

WHEREAS, pursuant to Section 10.4 of the Plan, the Board may amend the Plan at any time; and

WHEREAS, the Board believes it is in the best interests of the Company and its stockholders to, among other things, amend the Plan as set forth herein.

NOW THEREFORE, BE IT RESOLVED: that the Plan is hereby amended as follows, effective as of the Effective Date:

AMENDMENT

1. Section 4.5 of the Plan is hereby deleted and replaced in its entirety with the following:

> "Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee Director as compensation for services as a non-employee Director during any fiscal year of

the Company may not exceed $750,000 increased to $1,000,000 in the fiscal year of a non-employee Director's initial service as a non-employee Director (the "***Director Limit***"). The Administrator may make exceptions to this limit for individual non-employee Directors in extraordinary circumstances, as the Administrator may determine in its discretion."

2. This Amendment shall be and is hereby incorporated into and forms a part of the Plan.

3. Except as expressly provided herein, all terms and conditions of the Plan shall remain in full force and effect.

* * * * *

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: May 3, 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: May 3, 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 March 31, 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: May 3, 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 March 31, 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: May 3, 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.