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, 2023
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 28, 2023, there were 59,954,618 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, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 287,962	$ 243,784
Investments, short-term	55,916	79,331
Trade receivables, net	52,575	54,740
Inventory, net	4,090	4,297
Prepaid expenses	11,399	9,347
Other current assets	6,145	8,786
Total current assets	418,087	400,285
NONCURRENT ASSETS:		
Property and equipment, net	470	573
Restricted cash	750	750
Investments, long-term	48,538	22,568
Intangible assets, net	154,992	160,953
Deferred tax asset	89,385	85,943
Other noncurrent assets	2,870	2,798
Total noncurrent assets	297,005	273,585
TOTAL ASSETS	$ 715,092	$ 673,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,414	$ 3,786
Accrued compensation	5,691	11,532
Accrued expenses	56,810	59,942
Current portion of long-term debt	6,500	2,000
Other current liabilities	9,948	1,624
Total current liabilities	85,363	78,884
NONCURRENT LIABILITIES:		
Long-term debt, net	185,063	189,647
Other noncurrent liabilities	1,625	2,501
Total noncurrent liabilities	186,688	192,148
TOTAL LIABILITIES	272,051	271,032
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2023 and December 31, 2022, respectively; 59,954,618 shares and 59,615,731 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	1	1
Additional paid in capital	685,716	675,118
Accumulated other comprehensive income (loss)	(31)	(151)
Accumulated deficit	(242,645)	(272,130)
TOTAL STOCKHOLDERS' EQUITY	443,041	402,838
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 715,092	$ 673,870

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,	
	2023	2022
Net product revenues	$ 119,126	$ 85,313
Cost of product sold	20,780	14,716
Gross profit	98,346	70,597
Operating expenses:		
Research and development	13,289	7,578
Sales and marketing	22,572	17,583
General and administrative	22,062	17,880
Total operating expenses	57,923	43,041
Operating income	40,423	27,556
Other income (expense), net	2	(2)
Interest expense, net	(2,645)	(4,169)
Income before income taxes	37,780	23,385
Income tax expense	(8,295)	(1,900)
Net income	$ 29,485	$ 21,485
Unrealized gain on investments	120	—
Comprehensive income	$ 29,605	$ 21,485
EARNINGS PER SHARE:		
Basic	$ 0.49	$ 0.36
Diluted	$ 0.48	$ 0.35
Weighted average number of shares of common stock - basic	59,732,157	58,908,526
Weighted average number of shares of common stock - diluted	61,221,511	60,586,875

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance as of December 31, 2022	59,615,731	$ 1	$ 675,118	$ (151)	$ (272,130)	$ 402,838
Net income	—	—	—	—	29,485	29,485
Unrealized loss on investments	—	—	—	120	—	120
Exercise of options and restricted stock units	338,887	—	3,395	—	—	3,395
Stock-based compensation	—	—	7,203	—	—	7,203
Balance as of March 31, 2023	59,954,618	$ 1	$ 685,716	$ (31)	$ (242,645)	$ 443,041

	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 stock 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

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,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 29,485	$ 21,485
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	103	117
Intangible amortization	5,961	5,082
Stock-based and employee stock purchase compensation expense	7,203	4,628
Stock appreciation rights market adjustment	(642)	268
Debt issuance costs amortization	416	412
Deferred taxes	(3,442)	—
Amortization of premiums and accretion of discounts on Investment securities	(636)	—
Other non-cash expenses	369	385
Change in operating assets and liabilities:		
Trade receivables	2,165	(3,290)
Inventory	207	(165)
Prepaid expenses and other assets	592	(2,235)
Trade payables	2,628	5,903
Accrued expenses and other current liabilities	(1,850)	(3,586)
Other non-current liabilities	—	(152)
Net cash provided by operating activities	42,559	28,852
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investment securities	(47,776)	—
Proceeds from maturities and sales of investment securities	45,986	—
Purchase of property and equipment	—	(45)
Milestone payments	—	(40,000)
Net cash used in investing activities	(1,790)	(40,045)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal repayment of long term debt	(500)	(500)
Proceeds from exercised options	3,909	1,883
Net cash provided by financing activities	3,409	1,383
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	44,178	(9,810)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	244,534	235,059
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 288,712	$ 225,249
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 5,017	$ 3,829

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share data)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

The Company

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

2. LIQUIDITY AND CAPITAL RESOURCES

The unaudited condensed consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of $242,645 and $272,130, as of March 31, 2023 and December 31, 2022, respectively. As of March 31, 2023, the Company had cash, cash equivalents and investments of $392,416.

The Company believes that its existing cash, cash equivalents and investments on hand as of March 31, 2023, 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, 2023, the unaudited condensed consolidated statements of cash flows for the three months ended March 31, 2023, and 2022, 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, 2023 and 2022, are unaudited. The balance sheet as of March 31, 2023, was derived from audited financial statements as of and for the year ended December 31, 2022. 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, 2022, 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, 2023, and the results of its operations and its cash flows for the three months ended March 31, 2023 and 2022. The unaudited condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial

statements and accompanying notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Use of Estimates

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

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents and restricted cash consist of cash and, if applicable, highly liquid investments with an original maturity of three months or less when purchased, including investments in Money Market Funds and debt securities that approximate fair value. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that equal the amount reflected in the statements of cash flows.

	As of	
	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 287,962	$ 243,784
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 288,712	$ 244,534

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

Investments

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

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

Concentrations of Risk

Substantially all of the Company's cash and money market funds are held in two financial institutions. Due to their size, the Company believes these financial institutions represent minimal credit risk. Deposits may exceed the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation for U.S. institutions. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company believes that it is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

The Company is also subject to credit risk from its trade receivables related to its product sales. The Company extends credit to specialty pharmaceutical distribution companies within the United States. Customer creditworthiness is monitored and collateral is not required. Historically, the Company has not experienced credit losses on its accounts receivable. The Company monitors its exposure within accounts receivable and would record a reserve against uncollectible accounts receivable if necessary As of March 31, 2023, three customers accounted for 100% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 41% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 30% of gross accounts receivable; and PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 29% of gross accounts receivable. As of December 31, 2022, three customers accounted for 100% of gross accounts receivable; CVS Caremark, which accounted for 41% of gross accounts receivable, Accredo, which accounted for 35% of gross accounts receivable; and Pantherx, which accounted for 24% of gross accounts receivable.

For the three months ended March 31, 2023, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 35% of gross product revenues; Pantherx accounted for 33% of gross product revenues; and Accredo accounted for 32% of gross product revenues. 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.

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

Recently Issued Accounting Pronouncements

ASU 2020-04, Reference Rate Reform (Topic 848). In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*, which provides guidance related to reference rate reform. The pronouncement provides temporary optional expedients and exceptions to the current guidance on contract modifications and hedge accounting to ease the financial reporting burden related to the expected market transition from the London Interbank Offered Rate ("LIBOR") and other interbank offered rates to alternative reference rates. The guidance was effective upon issuance and could initially be applied to applicable contract modifications through December 31, 2022, which was extended to December 31, 2024 upon the FASB issuing ASU No. 2022-06, *Reference Rate Reform* (Topic 848): Deferral of the Sunset Date of Topic 848. The Company is currently evaluating the impact of the transition from LIBOR to alternative reference rates but does not expect a significant impact to its condensed consolidated financial statements.

4. INVESTMENTS

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

	March 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	$ 24,106	8	(22)	$ 24,092
Corporate debt securities	29,117	1	(49)	29,069
U.S. government securities	2,751	7	(3)	2,755
Total short-term investments	$ 55,974	16	(74)	$ 55,916
Long-term:				
Commercial paper	$ 1,580	—	—	$ 1,580
Corporate debt securities	25,855	36	(66)	25,825
U.S. government securities	21,076	61	(4)	21,133
Total long-term investments	$ 48,511	97	(70)	$ 48,538

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	$ 26,553	15	(34)	$ 26,534
Corporate debt securities	49,213	9	(73)	49,149
U.S. government securities	3,658	—	(10)	3,648
Total short-term investments	$ 79,424	24	(117)	$ 79,331
Long-term:				
Commercial paper	$ 853	1	—	$ 854
Corporate debt securities	21,516	11	(68)	21,459
U.S. government securities	257	—	(2)	255
Total long-term investments	$ 22,626	12	(70)	$ 22,568

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

5. FAIR VALUE MEASUREMENTS

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

It is the Company's policy to measure non-financial assets and liabilities at fair value on a nonrecurring basis. These non-financial assets and liabilities are not measured at fair value on an ongoing basis but are

subject to fair value adjustments in certain circumstances (such as evidence of impairment), which, if material, are disclosed in the accompanying footnotes.

The Company measures certain assets and liabilities at fair value based on the fair value hierarchy that prioritizes inputs to valuation techniques used to measure fair value into three levels based on the source of inputs as follows:

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

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

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

Money market funds are classified as Level 1 fair value instruments. Investments in available-for-sale debt securities are classified as Level 2 and carried at fair value, which we estimate utilizing a third-party pricing service. The pricing service utilizes industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. We validate valuations obtained from third-party services by obtaining market values from other pricing sources. The Company did not classify any assets or liabilities as Level 3 as of March 31, 2023 or December 31, 2022.

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

	March 31, 2023			December 31, 2022		
	Total	Level 1	Level 2	Total	Level 1	Level 2
Assets						
Cash equivalents	$ 185,534	184,790	744	$ 184,977	184,977	—
Commercial paper	25,672	—	25,672	27,388	—	27,388
Corporate debt securities	54,894	—	54,894	70,608	—	70,608
U.S. government securities	23,888	—	23,888	3,903	—	3,903
Total	$ 289,988	184,790	105,198	$ 286,876	184,977	101,899

6. INVENTORY

Inventory, net consisted of the following:

	As of	
	March 31, 2023	December 31, 2022
Raw materials	$ 776	$ 838
Work in process	1,690	1,513
Finished goods	2,243	2,565
Inventory, gross	4,709	4,916
Reserve for excess inventory	(619)	(619)
Total inventory, net	$ 4,090	$ 4,297

7. INTANGIBLE ASSETS

In August 2019, the Company received FDA approval of WAKIX® (pitolisant) for the treatment of excessive daytime sleepiness ("EDS") in adult patients with narcolepsy. This event triggered a milestone payment of $75,000 under the provisions of the 2017 LCA (defined below) which the Company capitalized as an intangible asset. The Company determined a useful life of 10 years for such intangible asset, and, as of March 31, 2023, the remaining useful life was 6.5 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 2017 LCA which the Company capitalized as an intangible asset and paid in January of 2021. The Company determined a useful life of 9 years for such intangible asset, and, as of March 31, 2023, the remaining useful life was 6.5 years.

In February 2022, the Company attained $500,000 in life-to-date aggregate net sales of WAKIX in the United States. This event triggered a final $40,000 payment under the provisions of the 2017 LCA which the Company capitalized as an intangible asset and paid in March of 2022. The Company determined a useful life of 7.6 years for such intangible asset, and, as of March 31, 2023, the remaining useful life was 6.5 years.

Amortization expense was $5,961 and $5,082 for the three months ended March 31, 2023 and 2022, respectively, and is recorded in general and administrative expenses on the unaudited condensed consolidated statements of operations and comprehensive income.

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

Years ending December 31,	
2023 (Excluding the three months ended March 31, 2023)	$ 17,884
2024	23,845
2025	23,845
2026	23,845
2027	23,845
Thereafter	41,728
Total	$ 154,992

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

	As of	
	March 31, 2023	**December 31, 2022**
Gross Carrying Amount	$ 215,000	$ 215,000
Accumulated Amortization	(60,008)	(54,047)
Net Book Value	$ 154,992	$ 160,953

8. LICENSE AGREEMENTS AND ASSET PURCHASE AGREEMENTS

License Agreements

In July 2017, Harmony entered into a License Agreement (the "2017 LCA") with Bioprojet Société Civile de Recherche ("Bioprojet") whereby Harmony acquired the exclusive right to commercialize the pharmaceutical compound pitolisant for the treatment, and/or prevention, of narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, and Parkinson's disease as well as any other indications unanimously agreed by the parties in the United States and its territories. A milestone payment of $50,000 was due upon acceptance by the FDA of pitolisant's NDA, which was achieved in February 2019 and was expensed within research and development

for the year ended December 31, 2019. A milestone payment of $77,000, which included a $2,000 fee that is described below, was due upon FDA approval of WAKIX (pitolisant) for treatment of EDS in adult patients with narcolepsy, which was achieved in August 2019. The $2,000 payment and $75,000 milestone payment were paid in August and November 2019, respectively. In addition, a milestone payment of $102,000, which included a $2,000 fee was due upon the FDA approval of the NDA for WAKIX for the treatment of cataplexy in adult patients with narcolepsy. The $2,000 payment was paid in October 2020 and a $100,000 milestone payment was paid in January 2021. A final $40,000 milestone payment was paid to Bioprojet in March 2022 upon WAKIX attaining $500,000 in aggregate net sales in the United States. The 2017 LCA also requires a fixed trademark royalty and a tiered royalty based on net sales, which is payable to Bioprojet on a quarterly basis. The Company incurred $19,060 and $13,672 for the three months ended March 31, 2023 and 2022, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of March 31, 2023 and December 31, 2022, the Company had accrued $19,060 and $25,367, respectively, for sales-based, trademark and tiered royalties.

On July 31, 2022, Harmony entered into a License and Commercialization Agreement (the "2022 LCA") with Bioprojet whereby Harmony obtained exclusive rights to manufacture, use and commercialize one or more new products based on pitolisant in the United States and Latin America, with the potential to add additional indications and formulations upon agreement of both parties. Harmony paid an initial, non-refundable $30,000 licensing fee in October 2022 and additional payments of up to $155,000 are potentially due under the 2022 LCA upon the achievement of certain future development and sales-based milestones. In addition, there are other payments due upon achievement of development milestones for new indications and formulations as agreed upon by both parties. The 2022 LCA also requires a fixed trademark royalty and a tiered royalty based on net sales upon commercialization, which will be payable to Bioprojet on a quarterly basis.

Agreement Related to Intellectual Property

In August 2021, the Company entered into an asset purchase agreement with ConSynance Therapeutics, Inc. (the "APA") to acquire HBS-102 (formerly referred to as "CSTI-100"), a potential first-in-class molecule with a novel mechanism of action. Under the terms of the APA, the Company acquired full development and commercialization rights globally, with the exception of Greater China, for $3,500. The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the assets acquired was concentrated in a single identified asset. In March 2023, the Company achieved a preclinical milestone, which triggered a $750 payment under the provisions of the APA, which the Company recognized as an IPR&D charge recorded in research and development within the unaudited condensed consolidated statement of operations and comprehensive income for the three months ended March 31, 2023. There are additional payments due under the APA upon the achievement of certain milestones including $1,000 for preclinical milestones, $19,000 for development milestones, $44,000 for regulatory milestones and $110,000 for sales milestones.

9. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	March 31, 2023	December 31, 2022
Royalties due to third parties	$ 19,060	$ 25,367
Rebates and other sales deductions	28,933	27,860
Interest	3,831	3,286
Selling and marketing	1,358	1,135
Research and development	1,075	358
Professional fees, consulting, and other services	708	1,163
Other expenses	1,845	773
	$ 56,810	$ 59,942

10. DEBT

Blackstone Credit Agreement

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

The repayment schedule for the Initial Term Loan consists of quarterly $500 principal payments, which commenced on December 31, 2021, and increasing to quarterly $5,000 principal payments beginning on March 31, 2024, with a $145,500 payment due on the maturity date of August 9, 2026 (“Maturity Date”). Interest is payable quarterly, which commenced on November 9, 2021, and continues through the Maturity Date. The Initial Term Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%.

Net cash received from the Initial Term Loan was $191,849, net of debt issuance costs of $8,151. The debt issuance costs related to the Initial Term Loan are being amortized as additional interest expense over the five-year loan term of the Blackstone Credit Agreement. In addition, the Company paid $1,000 in debt issuance costs relating the DDTL, which are recorded in other current assets within the unaudited condensed consolidated balance sheet. The fair value of the Initial Term Loan as of March 31, 2023 was $168,569.

Long-term debt, net consists of the following:

	March 31, 2023	December 31, 2022
Liability component - principal	$ 197,000	$ 197,500
Unamortized debt discount associated with debt financing costs	(5,437)	(5,853)
Liability component - net carrying value	191,563	191,647
Less current portion	(6,500)	(2,000)
Long-term debt, net	$ 185,063	$ 189,647

Future minimum payments relating to long-term debt, net as of March 31, 2023, for the periods indicated below consists of the following:

Years ending December 31,	
2023 (Excluding the three months ended March 31, 2023)	$ 1,500
2024	20,000
2025	20,000
2026	155,500
2027	—
Thereafter	—
Total	$ 197,000

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

	Three Months Ended March 31,	
	2023	2022
Interest on principal balance	$ 5,315	$ 3,824
Amortization of deferred financing costs	416	412
Total term loan interest expense	$ 5,731	$ 4,236

11. LEASES

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

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

The Company recorded operating lease costs of $378 and $385 for the three months ended March 31, 2023 and 2022, respectively.

As of March 31, 2023, the weighted-average remaining lease term for operating leases was 1.5 years and the weighted-average discount rate for operating leases was 4.6%.

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

Leases	Classification	March 31, 2023	December 31, 2022
Assets			
Operating lease right-of-use assets	Other noncurrent assets	$ 2,384	$ 2,312
Liabilities			
Operating lease liability, current portion	Other current liabilities	$ 1,874	$ 1,614
Operating lease liability, long-term	Other long-term liabilities	741	975
Total operating lease liabilities		$ 2,615	$ 2,589

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

	March 31, 2023	March 31, 2022
Operating cash flows from operating leases	$ 428	$ 434
Right of use assets obtained in exchange for operating lease obligations	$ 526	$ 234

Future payments under noncancelable operating leases with initial terms of one year or more as of March 31, 2023 consisted of the following:

Years ending December 31,	
2023 (Excluding the three months ended March 31, 2023)	$ 1,462
2024	1,102
2025	143
2026	10
2027	—
Thereafter	—
Total lease payments	2,717
Less: imputed interest	(102)
Total lease liabilities	$ 2,615

12. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company is subject to claims and suits arising in the ordinary course of business. The Company accrues such liabilities when they are known, if they are deemed probable and can be reasonably estimated. As of March 31, 2023, there were no material claims or suits outstanding.

13. STOCKHOLDERS' EQUITY

Common Stock

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

14. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

2020 Stock Incentive Plan

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

Stock options and stock appreciation rights under the 2020 Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). RSUs vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). As of March 31, 2023, there were 4,647,087 shares of common stock available for issuance under the 2020 Plan. The number of shares that may be issued under the 2020 Plan will automatically increase on January 1 of each year in an amount equal to the lesser of (i) 4.0% of the shares of the Company's common stock outstanding on December 31 of the preceding year or (ii) an amount determined by the Company's board of directors.

2017 Stock Incentive Plan

In August 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 shares of common stock 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, 2023:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2022	6,460,947	$ 30.90	7.86
Awards issued	99,797	$ 41.52	
Awards exercised	(324,301)	$ 12.06	
Awards forfeited	(158,798)	$ 21.61	
Awards outstanding—March 31, 2023	6,077,645	$ 32.32	7.77

Stock Appreciation Rights

The following table summarizes SARs activity for the three months ended March 31, 2023:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2022	43,208	$ 9.38	6.32
Awards issued	—	$ —	
Awards exercised	—	$ —	
Awards forfeited	—	$ —	
Awards outstanding—March 31, 2023	43,208	$ 9.38	6.08

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2023:

	Number of Awards	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2022	60,000	$ 29.03	8.24
Awards issued	—	$ —	
Awards vested	(30,000)	$ 29.03	
Awards forfeited	—	$ —	
Awards outstanding—March 31, 2023	30,000	$ 29.03	7.99

As of March 31, 2023 and December 31, 2022, stock awards issued under the 2017 and 2020 Plans of 2,219,090 and 1,818,045 shares of common stock, respectively, were vested.

Value of Stock Options and SARs

The Company values options and SARs using the Black-Scholes option-pricing model. The Company lacks sufficient historical company-specific volatility information. Therefore, the Company estimates expected stock volatility based on historical volatility of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. For SARs, the expected term is based upon the weighting of certain future events. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for the time periods approximately equal to the expected term of the award. An expected dividend yield of 0% is based on the fact that the Company has never paid cash dividends and does not expect to do so in the foreseeable future.

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

	As of	
	March 31, 2023	December 31, 2022
Dividend yield	0.00 %	0.00 %
Expected volatility	76.32 %	72.57 - 77.08 %
Risk-free interest rate	3.55 - 3.63 %	1.99 - 4.05 %
Lack of marketability discount	0.00 %	0.00 %
Expected term (years)	2.9 - 6.3	3.1 - 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 $19.83 and $18.88 on March 31, 2023 and December 31, 2022, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense, net for the three months ended March 31, 2023 and 2022, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income in the following line items:

	Three Months Ended March 31,	
	2023	2022
Research and development expense	$ 976	$ 518
Sales and marketing expense	1,073	976
General and administrative expense	4,512	3,402
	$ 6,561	$ 4,896

Stock-based compensation expense, net related to options and RSUs issued under the 2017 Plan and 2020 Plan is included in stockholder's equity, and a liability for SARs is included in other non-current liabilities, in the Company's unaudited condensed consolidated balance sheet. As of March 31, 2023, the total unrecognized stock-based compensation expense related to options and RSUs was $77,333. Such amount will be recognized in the Company's consolidated statement of operations over a weighted average period of 2.8 years.

Employee Stock Purchase Plan

The 2020 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. There were no shares issued under the ESPP for each of the three months ended March 31, 2023 and 2022. The discount on the ESPP was $105 and $94 for the three months ended March 31, 2023 and 2022, respectively, and is recorded within stock-based compensation expense.

15. EARNINGS PER SHARE

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

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

	Three Months Ended March 31,	
	2023	2022
Numerator		
Net income	$ 29,485	$ 21,485
Denominator		
Net income per common share - basic	$ 0.49	$ 0.36
Net income per common share - diluted	$ 0.48	$ 0.35
Weighted average number of shares of common stock - basic	59,732,157	58,908,526
Weighted average number of shares of common stock - diluted	61,221,511	60,586,875

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

	Three Months Ended March 31,	
	2023	2022
Stock options, SARs, and RSUs to purchase common stock	1,489,354	1,678,349

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

	Three Months Ended March 31,	
	2023	2022
Stock options, SARs, and RSUs to purchase common stock	4,661,499	5,249,666

16. INCOME TAXES

The reasons for the difference between the statutory federal income tax rate and the Company's effective income tax rate for the three months ended March 31, 2023 and 2022 are as follows:

	Three Months Ended March 31,	
	2023	2022
Federal income tax rate	21.0 %	21.0 %
Stock-based compensation	(2.8)	(3.8)
State taxes	6.3	6.4
Credits	(2.9)	—
Other	0.4	—
Valuation allowance	—	(15.5)
Total	22.0 %	8.1 %

17. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon Biosciences, LLC ("Paragon"). The related party is an entity that shares common ownership

with the Company. In addition, the Chairman of the Company's board of directors was the President and owner of the entity. The Company terminated the management agreement upon the consummation of its IPO. The Company is also party to a right of use agreement with the related party whereby it has access to and the right to use certain office space leased by the related party in Chicago, IL. 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, 2023 and 2022, 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, 2023 and December 31, 2022, 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, business strategy, products, prospective products, product approvals, research and development costs, anticipated timing and likelihood of success of clinical trials, expected timing of the release of clinical trial data, the plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, statements about:

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

- our failure to maintain effective internal controls; and
- the impact of government laws and regulations.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the section in our most recent Annual Report on Form 10-K entitled “Item 1A. Risk Factors” and the sections in this Quarterly Report on Form 10-Q titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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

Unless otherwise indicated, information contained in this Quarterly Report on Form 10-Q concerning our industry, including industry statistics and forecasts, competitive position and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and other third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, projections, forecasts, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described in “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements.” These and other factors could cause results to differ materially from those expressed and forecasts in the estimates made by the independent parties and by us.

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

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

Further, we have in-licensed from Bioprojet the registered trademark product name WAKIX® in the United States. We also have registered trademark protection in the United States for KNOW NARCOLEPSY®, REM AT THE WRONG TIME® and NON-REM AT THE WRONG TIME®, as well as our brand and logo HB®, HB HARMONY BIOSCIENCES® and HARMONY BIOSCIENCES®. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

Company Overview

We are a commercial-stage, pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action ("MOA") specifically designed to increase histamine signaling in the brain by binding to H_3 receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of excessive daytime sleepiness ("EDS") in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. In October 2020, WAKIX was approved by the FDA for the treatment of cataplexy in adult patients with narcolepsy. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration (the "DEA").

We believe that pitolisant's ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological diseases that are mediated through H_3 receptors and histamine signaling. We are taking a mechanism-based approach to managing the life cycle of pitolisant and have identified idiopathic hypersomnia ("IH"), another central disorder of hypersomnolence like narcolepsy, as our next potential new indication for WAKIX. In April 2022, we initiated a Phase 3 registrational trial, the INTUNE Study, to evaluate the efficacy and safety of pitolisant in adult patients with IH. We continue to see strong momentum in the INTUNE Study and we anticipate topline data in the fourth quarter of 2023. We are focusing our development efforts on other rare neurological disorders in which EDS is a prominent symptom, including Prader-Willi Syndrome ("PWS") and myotonic dystrophy, otherwise known as dystrophia myotonica ("DM"). Based on the data from our Phase 2 proof-of-concept clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS, an end-of-phase 2 meeting with the FDA is scheduled in late second quarter of 2023. We intend to advance our development program in patients with PWS to a Phase 3 trial. In June 2021, we initiated a Phase 2 proof-of-concept clinical trial to evaluate pitolisant for the treatment of EDS, fatigue and cognitive dysfunction in adult patients with DM1 and anticipate topline results from this trial in the fourth quarter of 2023.

Our partner, Bioprojet, completed a Phase 3 trial in pediatric patients with narcolepsy and submitted the trial data to the European Medical Agency ("EMA") seeking approval for a pediatric narcolepsy indication. On March 15, 2023, Bioprojet received an approval from the EMA's Committee for Medicinal Products for Human Use ("CHMP") for a pediatric narcolepsy indication. We are working with Bioprojet towards the submission to the FDA of a supplemental NDA for pediatric narcolepsy. In addition, we are working with the FDA to gain alignment in pursuit of pediatric exclusivity for WAKIX.

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

In addition, in August 2021, we entered into an asset purchase agreement with ConSynance Therapeutics, Inc. (the "APA") to acquire 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. In connection with the acquisition, we made an upfront payment of $3.5 million and will be required to make additional 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. 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 is ongoing.

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

We were founded in July 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company. We converted to a Delaware corporation named Harmony Biosciences II, Inc. in September 2017, and, in February 2020, we changed our name to Harmony Biosciences Holdings, Inc. Our operations are conducted by our wholly owned subsidiary, Harmony Biosciences, LLC, which was formed in May 2017. Our operations to date have consisted of building and staffing our organization, acquiring the rights to pitolisant, raising capital, opening an investigational new drug application ("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 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, 2023, we continued to see growth in the number of unique healthcare professional ("HCP") prescribers of WAKIX since it became available in November 2019. The average number of patients on WAKIX for the three months ended March 31, 2023 was approximately 5,100. Additionally, as of March 31, 2023, 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.

Financial Operations Overview

Revenue

Net product sales includes gross sales of WAKIX less provisions for sales discounts and allowances, which includes trade allowances, rebates to government and commercial entities, and discounts. Although we expect net sales to increase over time, provisions for sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in our estimates.

Cost of Product Sales

Cost of product sales includes manufacturing and distribution costs, the cost of the drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs and salaries of employees involved with production. We expect the cost of product sales to increase as we continue to ramp up production in order to meet future demand for WAKIX and diversify our supply chain for WAKIX.

The shelf life of WAKIX is three years from date of manufacture, with the earliest expiration of current inventory expected to be February 2024. We regularly review our inventory levels and expect write-offs from time to time. We will continue to assess inventory levels in future periods as demand for WAKIX and the rate

of inventory turnover evolves. We currently expect to have adequate supply of WAKIX into the first quarter of 2024, with additional API on-hand inventory to support at least 36 months beyond this time frame.

Research and Development Expenses

Research and development expenses primarily include development programs for potential new indications for pitolisant in patients with IH, PWS and DM. We also incur research and development expenses related to our team of Medical Science Liaisons ("MSLs") who interact with key opinion leaders, with a focus on the science, the role of histamine in sleep-wake state stability and the novel mechanism of action of pitolisant. In addition, our MSLs support our market access team with the presentation of clinical data to payors upon request and our clinical development team to identify potential clinical trial sites. Research and development costs are expensed as incurred. We have significantly increased our research and development efforts as we advance our clinical programs in IH, PWS and DM and assess other product candidates to expand our pipeline. Research and development expenses also include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our research and development personnel;
- direct third-party costs such as expenses incurred under agreements with CROs, and contract manufacturing organizations ("CMOs");
- manufacturing costs in connection with producing materials for use in conducting clinical trials;
- costs related to packaging and labeling of clinical supplies;
- other third-party expenses (e.g., 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, including our ability to access sleep labs in order to conduct objective sleep testing, that could be impacted by future shelter-in-place orders and needs of the health care system to focus on managing patients affected by COVID-19;

- receiving Bioprojet's consent to pursue additional indications for pitolisant;

- the acceptance of INDs for our planned clinical trials or future clinical trials;

- the successful and timely enrollment and completion of clinical trials;

- the successful completion of preclinical studies and clinical trials;

- successful data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended populations;

- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;

- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;

- the entry into collaborations to further the development of our product candidates;

- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; and

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

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

Sales and Marketing Expenses

Our sales and marketing expenses primarily relate to the market development and commercialization activities of WAKIX for the treatment of EDS and cataplexy in adult patients with narcolepsy. Market development and commercial activities account for a significant portion of our operating expenses and are expensed as incurred. We expect our sales and marketing expenses to increase in the near- and mid-term to support WAKIX's 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, marketing and market access personnel;

- healthcare professional-related expenses, including marketing programs, healthcare professional promotional medical education, disease education, conference exhibits and market research;

- patient-related expenses, including patient awareness and education programs, disease awareness education, patient reimbursement programs, patient support services and market research;

- market access expenses, including payor education, specialty pharmacy programs and services to support the continued commercialization of WAKIX; and

- secondary data purchases (i.e., patient claims and prescription data), data warehouse development and data management.

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future to support our continued commercialization efforts, ongoing and future potential research and development activities, and increased costs of operating as a public company. These increases will likely be driven by costs associated with the hiring of additional personnel and fees paid to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs. If any of our current or future indication expansion programs or new product candidates obtain U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Paragon Agreements

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

We are also party to a right-of-use agreement with Paragon whereby we have access to and the right to use certain office space leased by Paragon in Chicago, Illinois. For the three months ended March 31, 2023, we paid fees of $0.1 million pursuant to this agreement.

Interest Expense, Net

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

Results of Operations

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

	Three Months Ended March 31,	
	2023	2022
	(In thousands)	
Net product revenue	$ 119,126	$ 85,313
Cost of product sales	20,780	14,716
Gross profit	98,346	70,597
Operating expenses:		
Research and development	13,289	7,578
Sales and marketing	22,572	17,583
General and administrative	22,062	17,880
Total operating expenses	57,923	43,041
Operating income	40,423	27,556
Other income (expense), net	2	(2)
Interest expense, net	(2,645)	(4,169)
Net income before provision for income taxes	37,780	23,385
Income tax expense	(8,295)	(1,900)
Net income	$ 29,485	$ 21,485

Net Product Revenue

Net product revenue increased by $33.8 million, or 39.6%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase was due to the growth in the average number of patients on WAKIX from 4,300 during the three months ended March 31, 2022 to 5,100 during the three months ended March 31, 2023, and price increases.

Cost of Product Sales

Cost of product sales increased by $6.1 million, or 41.2%, for the three months ended March 31, 2023, compared to the same period in 2022. 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 $5.7 million, or 75.4%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase for the three months ended March 31, 2023 was primarily driven by increased clinical development work associated with IH, PWS and DM, an IPR&D charge related milestone related to preclinical milestones achieved for HBS-102 and increased personnel costs.

Sales and Marketing Expenses

Sales and marketing expenses increased by $5.0 million, or 28.4%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase was primarily due to patient engagement and marketing activities driven by our commercialization of WAKIX and increased personnel costs related to sales force expansion.

General and Administrative Expenses

General and administrative expenses increased by $4.2 million, or 23.4%, for the three months ended March 31, 2023, as compared to the same period in 2022. The increase was primarily due to an increase to stock compensation associated with new awards, an increase in personnel cost, and an increase in intangible asset amortization as a result of the $40.0 million milestone payment in March 2022 upon attaining $500.0 million in life-to-date aggregate net sales of WAKIX in the United States.

Interest Expense, Net

Interest expense, net decreased by $1.5 million, or 36.6%, for the three months ended March 31, 2023, compared to the same period in 2022 primarily due to interest income generated from our investments and cash equivalents, partially offset by higher interest rates on our debt as a result of the increase to the LIBOR.

Income Taxes

Income tax expense was $8.3 million, representing a 22.0% effective tax rate, for the three months ended March 31, 2023, and $1.9 million, or an effective tax rate of 8.1%, as compared to the same period in 2022. The increase in our effective tax rate was primarily driven by the utilization of net operating loss ("NOL") carryforwards during 2022, which reduced our effective rate tax in the prior year. We have utilized all of our federal NOL carryforwards as of December 31, 2022, and the utilization of state NOL carryforwards may be subject to a substantial limitation due to state provisions. The effective tax rate of 22.0% for the three months ended March 31, 2023 included 6.3% for the provision of state income taxes, partially offset by a tax windfall benefit of 2.8% from the exercise of stock options and a 2.9% benefit from credits.

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 debt agreements; (c) the proceeds from our IPO; and (d) the proceeds from the sale of common stock to Blackstone. From our inception through our IPO, we received aggregate proceeds of $345.0 million from sales of our convertible preferred stock. In August 2020, we completed the IPO of our common stock, in which we sold 6,151,162 shares of our common stock, including 802,325 shares of our common stock pursuant to the underwriters' over-allotment option. The shares were sold at a price of $24.00 per share for net proceeds of approximately $135.4 million. As of March 31, 2023, we had cash, cash equivalents, restricted cash and investments of $393.2 million and an accumulated deficit of $242.6 million. As of March 31, 2023, we had outstanding debt of $197.0 million.

We have invested a portion of our available cash in money market funds, U.S. government and agency securities, corporate bonds and commercial paper in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least A-2/P-2/F2 from at least two National Recognized Statistical Rating Organizations. Our investment portfolio may be adversely impacted by future disruptions in the credit markets.

The unaudited condensed consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

We believe that our anticipated cash from operating and financing activities, existing cash, cash equivalents and investments, as well as our ability to borrow additional funds under the Blackstone Credit Agreement, will enable us to meet our operational liquidity needs and fund our planned investing activities for

the next 12 months. We have based our liquidity and cash flow projections on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect.

Blackstone Credit Agreement

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

The repayment schedule for the Initial Term Loan consists of quarterly $0.5 million principal payments, which commenced on December 31, 2021 and increases to quarterly $5.0 million payments beginning on March 31, 2024, with a $145.5 million payment due on the maturity date of August 9, 2026 ("Maturity Date"). Interest is payable quarterly commencing on November 9, 2021 and continuing through the Maturity Date. The Initial Term Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%. The Loans are guaranteed by our subsidiary Harmony Biosciences, LLC.

The Blackstone Credit Agreement contains affirmative and negative covenants, including limitations on our ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Blackstone Credit Agreement contains a financial covenant that requires us to maintain at all times cash and cash equivalents in certain deposit accounts in an amount at least equal to $10.0 million. We were in compliance with all covenants as of March 31, 2023.

Agreement Related to Intellectual Property

In August 2021, we entered into the APA to acquire HBS-102, a potential first-in-class molecule with a novel mechanism of action. Under the terms of the agreement, we acquired full development and commercialization rights globally, with the exception of Greater China, for $3.5 million. Additionally, there are payments due upon the achievement of certain milestones, including $1.0 million for additional preclinical milestones (see "Recent Milestone Payment"), $19.0 million for development milestones, $44.0 million for regulatory milestones and $110.0 million for sales milestones.

License Agreement

In July 2022, we entered into the 2022 LCA with Bioprojet whereby we obtained exclusive rights to manufacture, use and commercialize one or more new products based on pitolisant in the United States and Latin America, with the potential to add additional indications and formulations upon the agreement of both parties. We paid an initial, non-refundable $30.0 million licensing fee in October 2022 and additional payments of up to $155.0 million are potentially due under the 2022 LCA upon the achievement of certain future development and sales-based milestones. In addition, certain payments will become due upon the achievement of development milestones for new indications and formulations as agreed upon by both parties. The 2022 LCA also includes a fixed trademark royalty and a tiered royalty based on net sales of any new products commercialized, which will be payable to Bioprojet on a quarterly basis.

Recent Milestone Payments

In March 2023, we achieved a preclinical milestone, which triggered a $0.8 million payment under the provisions of the APA, which we expect to pay in April 2023.

In March 2022, we made a final $40.0 million milestone payment to Bioprojet upon WAKIX attaining $500.0 million in life-to-date aggregate net sales in the United States.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
Selected cash flow data	(In thousands)	
Cash provided by (used in):		
Operating activities	$ 42,559	$ 28,852
Investing activities	(1,790)	(40,045)
Financing activities	3,409	1,383

Operating Activities

Net cash provided by operating activities for the three months ended March 31, 2023 consisted of our net income of $29.5 million adjusted for non-cash items of $3.4 million related to deferred tax assets, $6.1 million related to intangible amortization and depreciation and $6.6 million related to stock-based compensation expense. Net working capital excluding cash increased by $3.7 million.

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.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2023 was $1.8 million, which was primarily attributable to $47.8 million in purchases of debt securities, partially offset by $46.0 million in proceeds from sales and maturities of investments.

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 2017 LCA.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2023 was $3.4 million, which primarily consisted of $3.9 million in proceeds from exercised options offset by a $0.5 million principal payment associated with the Blackstone Credit Agreement.

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.

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, or 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 the amount of revenue recognized on sales of WAKIX, our costs incurred under services type agreements related to the performance of research and development activities, and the measurement of compensation expense pursuant to stock-based awards. We base our estimates on contractual terms, historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the quarter covered by this report, there were no material changes to the accounting policies and assumptions previously disclosed, except as disclosed in Note 3 to the unaudited condensed consolidated financial statements contained herein.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates. We invest a portion of our cash in investment-grade, interest-bearing securities. The primary objectives of our investment activities are to preserve principal, maintain liquidity and maximize total return. In order to achieve these objectives, we invest in money market funds, U.S. government and agency securities, corporate bonds and commercial paper in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least A-2/P-2/F2 from at least two National Recognized Statistical Rating Organizations. We do not have any direct investments in asset-backed securities, collateralized debt or loan obligations, or structured investment vehicles. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Based on our $290.0 million of investments in money market funds, U.S. treasury notes, corporate bonds and municipal obligations as of March 31, 2023, 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, 2023, we had $197.0 million in borrowings outstanding. The Initial Term Loan bears interest at an interest rate equal to LIBOR (subject to a 1.00% floor) plus 6.50%. Based on the $197.0 million of principal outstanding as of March 31, 2023, 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 each of the three months ended March 31, 2023 and 2022.

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, 2023. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2023, 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, 2023 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, 2022, 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.

On May 1, 2023, the Company's Board of Directors appointed Dr. Kumar Budur as the Company's new Chief Medical Officer following the appointment of Dr. Jeffrey Dayno as the Company's President and Chief Executive Officer on April 24, 2023. Dr. Budur has served in the role of SVP & Head of Clinical Development with the Company since March 21, 2022. Prior to joining Harmony Biosciences, Dr. Budur spent 6 years at each of AbbVie Inc. and Takeda Pharmaceutical Company, respectively. A nationally recognized expert in Research and Development, he has overseen programs ranging from late discovery, early clinical development to late clinical development, and post-marketing studies. He has experience in progressing small molecules, biologics, and drug-device combinations through various stages of development. Dr. Budur was involved with four New Drug Applications (NDAs) and was the lead for the registration of clinical trials, submission, and approval processes of two NDAs. Dr. Budur was trained at Cambridge University in the UK and Cleveland Clinic in the US and completed his residency in Psychiatry and fellowships in Neurophysiology and Sleep Medicine. He is Board Certified in Psychiatry and Sleep Medicine and holds a master's degree in clinical research from Case Western Reserve University. Dr. Budur has published over 45 original research papers in peer reviewed journals, edited four books, and chaired National and International seminars and symposiums.

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
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, 2023 formatted in Inline XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity and (vi) Notes to Financial Statements, tagged as blocks of text and including detailed tags.			
104*	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101)			

* Filed herewith.

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

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

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

By: /s/ Jeffrey M. Dayno
Name: Jeffrey M. Dayno
Title: President, Chief Executive Officer and Director (principal executive officer)
Date: May 2, 2023

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer (principal financial officer)
Date: May 2, 2023

Exhibit 31.1

Certification of Principal Executive Officer

I, Jeffrey M. Dayno, 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 2, 2023

By: /s/ Jeffrey M. Dayno

Jeffrey M. Dayno

President, Chief Executive Officer 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 2, 2023

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, 2023, 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 2, 2023

By: /s/ Jeffrey M. Dayno

Jeffrey M. Dayno
President, Chief Executive Officer 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, 2023 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 2, 2023

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.