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, 2024
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 26, 2024, there were 56,791,861 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 SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 332,981	$ 311,660
Investments, short-term	39,369	41,800
Trade receivables, net	79,719	74,140
Inventory, net	5,857	5,363
Prepaid expenses	12,894	12,570
Other current assets	8,683	5,537
Total current assets	479,503	451,070
NONCURRENT ASSETS:		
Property and equipment, net	213	371
Restricted cash	270	270
Investments, long-term	81,244	72,169
Intangible assets, net	131,147	137,108
Deferred tax asset	147,639	144,162
Other noncurrent assets	6,969	6,298
Total noncurrent assets	367,482	360,378
TOTAL ASSETS	$ 846,985	$ 811,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 15,144	$ 17,730
Accrued compensation	7,317	23,747
Accrued expenses	91,699	99,494
Current portion of long-term debt	15,000	15,000
Other current liabilities	25,093	7,810
Total current liabilities	154,253	163,781
NONCURRENT LIABILITIES:		
Long-term debt, net	174,996	178,566
Other noncurrent liabilities	2,342	2,109
Total noncurrent liabilities	177,338	180,675
TOTAL LIABILITIES	331,591	344,456
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 56,791,214 and 56,769,081 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	620,507	610,266
Accumulated other comprehensive (loss) income	(171)	2
Accumulated deficit	(104,943)	(143,277)
TOTAL STOCKHOLDERS' EQUITY	515,394	466,992
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 846,985	$ 811,448

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Net product revenue	$ 154,615	$ 119,126
Cost of product sold	27,484	20,780
Gross profit	127,131	98,346
Operating expenses:		
Research and development	22,189	13,289
Sales and marketing	27,233	22,572
General and administrative	25,676	22,062
Total operating expenses	75,098	57,923
Operating income	52,033	40,423
Other (expense) income, net	(141)	2
Interest expense	(4,535)	(5,731)
Interest income	4,428	3,086
Income before income taxes	51,785	37,780
Income tax expense	(13,451)	(8,295)
Net income	$ 38,334	$ 29,485
Unrealized (loss) income on investments	(173)	120
Comprehensive income	$ 38,161	$ 29,605
EARNINGS PER SHARE:		
Basic	$ 0.68	$ 0.49
Diluted	$ 0.67	$ 0.48
Weighted average number of shares of common stock - basic	56,771,251	59,732,157
Weighted average number of shares of common stock - diluted	57,597,627	61,221,511

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES

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

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance as of December 31, 2023	56,769,081	$ 1	$ 610,266	$ 2	$ (143,277)	$ 466,992
Net income	—	—	—	—	38,334	38,334
Unrealized loss on investments	—	—	—	(173)	—	(173)
Exercise of options and restricted stock units	22,133	—	(153)	—	—	(153)
Stock-based compensation	—	—	10,394	—	—	10,394
Balance as of March 31, 2024	56,791,214	$ 1	$ 620,507	$ (171)	$ (104,943)	$ 515,394

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	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 stock options	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

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 38,334	$ 29,485
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	163	103
Intangible amortization	5,961	5,961
Stock-based and employee stock purchase compensation expense	10,394	7,203
Stock appreciation rights market adjustment	40	(642)
Debt issuance costs amortization	180	416
Deferred taxes	(3,477)	(3,442)
Amortization of premiums and accretion of discounts on Investment securities	(594)	(636)
Other non-cash expenses	467	369
Change in operating assets and liabilities:		
Trade receivables	(5,579)	2,165
Inventory	(494)	207
Prepaid expenses and other assets	(3,439)	592
Trade payables	(2,586)	2,628
Other liabilities	(8,229)	(1,850)
Net cash provided by operating activities	31,141	42,559
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investment securities	(25,106)	(47,776)
Proceeds from maturities and sales of investment securities	18,925	45,986
Purchase of property and equipment	(5)	—
Net cash used in investing activities	(6,186)	(1,790)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal repayment of long term debt	(3,750)	(500)
Proceeds from exercised options	116	3,909
Net cash (used in) provided by financing activities	(3,634)	3,409
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	21,321	44,178
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	311,930	244,534
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 333,251	$ 288,712
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 4,585	$ 5,017

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES
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 subsidiaries (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"), and Zynerba Pharmaceuticals, Inc. The Company is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders as well as patients living with other neurological diseases who have unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

On October 10, 2023, the Company completed a tender offer to acquire all of the outstanding shares of common stock of Zynerba Pharmaceuticals, Inc. (together with its subsidiary, Zynerba Pharmaceutical Pty, Ltd., "Zynerba"). Zynerba is a clinical-stage pharmaceutical company focused on innovative pharmaceutically produced transdermal cannabidiol therapies for orphan neuropsychiatric disorders, including Fragile X Syndrome.

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 $104,943 and $143,277, as of March 31, 2024, and December 31, 2023, respectively. As of March 31, 2024, the Company had cash, cash equivalents and investments of $453,594.

The Company believes that its existing cash, cash equivalents and investments on hand as of March 31, 2024, 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, 2024, the unaudited condensed consolidated statements of cash flows for the three months ended March 31, 2024, and 2023, 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, 2024, and 2023, are unaudited. The balance sheet as of December 31, 2023, was derived from audited financial statements as of and for the year ended December 31, 2023. 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, 2023, 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, 2024, and the results of

its operations and its cash flows for the three months ended March 31, 2024, and 2023. 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, 2023.

Reclassifications

Certain prior period amounts within the unaudited condensed consolidated statements of operations and comprehensive income have been reclassified to conform to current period presentation. In particular, interest expense and interest income were previously classified together as interest expense, net and are now separately classified as interest expense and interest income, respectively. The reclassification of these items had no impact on net income, earnings per share or accumulated deficit in current or prior periods.

Significant Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to, clinical trial results of the Company's product candidates; the Company's ability to obtain regulatory approval to market its products; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, the Company's products, if approved; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its product candidates.

The Company currently has one commercially approved product, WAKIX, and there can be no assurance that the Company's research and development efforts will result in successfully commercialized products in addition to WAKIX. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts 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.

Operating Segments

The Company holds all its tangible assets, conducts its operations, and generates its revenue in the United States. Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Makers in deciding how to allocate resources to an individual segment and in assessing performance. The Company has determined it operates in a single operating segment and has one reportable segment.

Fair Value of Financial Instruments

The Company's 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, 2024, or December 31, 2023.

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 and the statements of cash flows.

	As of	
	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 332,981	$ 311,660
Restricted cash	270	270
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 333,251	$ 311,930

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. Interest income earned on cash and investment balances, accretion of the discount on investments in debt securities, amortization of premiums and realized gains and losses, if any, are recorded in interest income 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 five 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 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, 2024, three customers accounted for 100% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 41% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 36% of gross accounts receivable; and PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 23% of gross accounts receivable. As of December 31, 2023, three customers accounted for 100% of gross accounts receivable; Accredo, which accounted for 39% of gross accounts receivable, CVS Caremark, which accounted for 32% of gross accounts receivable; and Pantherx, which accounted for 29% of gross accounts receivable.

For the three months ended March 31, 2024, three customers accounted for 100% of gross product revenue; CVS Caremark accounted for 42% of gross product revenue; Accredo accounted for 33% of gross product revenue; and Pantherx accounted for 25% of gross product revenue. For the three months ended March 31, 2023, three customers accounted for 100% of gross product revenue; CVS Caremark accounted for 35% of gross product revenue; Pantherx accounted for 33% of gross product revenue; and Accredo accounted for 32% of gross product revenue.

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

Share Repurchases

The Company accounts for share repurchases as constructive retirements, whereby it reduces common stock and additional paid-in capital by the amount of the original issuance, with any excess purchase price recorded as a reduction to retained earnings. Under this method, issued and outstanding shares of common stock are reduced by the amount of shares of common stock repurchased, and no treasury stock is recognized on the condensed consolidated financial statements.

Business Combinations

Business combinations and asset acquisitions are accounted for in accordance with FASB ASC 805 Business Combinations. Refer to Note 4, *Acquisition*, for a more detailed discussion of the Zynerba Acquisition.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-07, *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 is intended to improve

reportable segment disclosures primarily through enhanced disclosure of reportable segment expenses and requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. This ASU is effective for annual reporting periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 is required to be applied retrospectively to all prior periods presented in the financial statements. The Company has one reportable segment and is currently evaluating the impact that ASU 2023-07 will have on its condensed consolidated financial statements.

In December 2023, the FASB issued Accounting Standards Update ("ASU") No 2023-09, *"Income Taxes (Topic 740): Improvements to Income Tax Disclosures"* ("ASU 2023-09"). ASU 2023-09 expands disclosures in the rate reconciliation and requires disclosure of income taxes paid by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2023-09 will have on its condensed consolidated financial statements.

4. ACQUISITION

In October 2023, the Company completed a tender offer to purchase the outstanding common stock of Zynerba ("Zynerba Common Stock") for (i) $1.1059 per share of Zynerba Common Stock (the "Common Cash Amount"), the aggregate amount of which was $60,000 and was paid at closing, plus (ii) one contingent value right (each, a "CVR") per share of Zynerba Common Stock (the "Common CVR Amount"), which represents the right to receive up to approximately $2.5444 per share of Zynerba Common Stock, subject to the achievement of certain clinical, regulatory and sales-based milestones. The Common CVR Amounts are to be paid in cash, subject to any applicable withholding of taxes and without interest. The aggregate amount of consideration to acquire Zynerba Common Stock was $60,000, excluding transaction related fees of $2,645 and was paid by the Company using cash on hand.

The Zynerba Acquisition was accounted for as an asset acquisition under ASC Topic 805, Business Combinations, because substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable IPR&D asset, ZYN002, Zynerba's lead asset. ZYN002 is the first and only pharmaceutically manufactured, synthetic cannabidiol, a non-euphoric cannabidiol, formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system and is currently in Phase III clinical trial for the potential treatment of Fragile X Syndrome. The Company recognized the acquired assets and assumed liabilities based on the consideration paid, including transaction costs, on a relative fair value basis, and after first allocating the preliminary excess of the fair value of net assets acquired over the purchase price consideration to certain qualifying assets, principally, the IPR&D asset.

5. 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, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	$ 23,038	10	(7)	$ 23,041
Corporate debt securities	16,316	16	(4)	16,328
Total short-term investments	$ 39,354	26	(11)	$ 39,369
Long-term:				
Corporate debt securities	51,062	61	(50)	51,073
U.S. government securities	30,368	—	(197)	30,171
Total long-term investments	$ 81,430	61	(247)	$ 81,244

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	$ 23,832	36	(3)	$ 23,865
Corporate debt securities	15,968	28	—	15,996
U.S. government securities	1,940	—	(1)	1,939
Total short-term investments	$ 41,740	64	(4)	$ 41,800
Long-term:				
Commercial paper	$ 744	—	—	$ 744
Corporate debt securities	42,688	81	(28)	42,741
U.S. government securities	28,795	7	(118)	28,684
Total long-term investments	$ 72,227	88	(146)	$ 72,169

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. The Company did not have any available-for-sale debt security investments in a continuous unrealized loss position of greater than 12 months as of March 31, 2024, and December 31, 2023, respectively.

6. FAIR VALUE MEASUREMENTS

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, 2024, or December 31, 2023.

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

	March 31, 2024			December 31, 2023		
	Total	Level 1	Level 2	Total	Level 1	Level 2
Assets						
Cash equivalents	$ 264,079	264,079	—	$ 244,569	243,685	884
Commercial paper	23,041	—	23,041	24,609	—	24,609
Corporate debt securities	67,401	—	67,401	58,737	—	58,737
U.S. government securities	30,171	—	30,171	30,623	—	30,623
Total	$ 384,692	264,079	120,613	$ 358,538	243,685	114,853

7. INVENTORY

Inventory, net consisted of the following:

	As of	
	March 31, 2024	December 31, 2023
Raw materials	$ 1,009	$ 1,060
Work in process	1,748	2,020
Finished goods	3,100	2,283
Total inventory, net	$ 5,857	$ 5,363

8. 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, 2024, the remaining useful life was 5.5 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, 2024, the remaining useful life was 5.5 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, 2024, the remaining useful life was 5.5 years.

Amortization expense was $5,961 for each of the three months ended March 31, 2024, and 2023 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,	
2024 (excluding the three months ended March 31, 2024)	$ 17,884
2025	23,845
2026	23,845
2027	23,845
2028	23,845
Thereafter	17,883
Total	$ 131,147

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

	As of	
	March 31, 2024	December 31, 2023
Gross Carrying Amount	$ 215,000	$ 215,000
Accumulated Amortization	(83,853)	(77,892)
Net Book Value	$ 131,147	$ 137,108

9. 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 $24,738 and $19,060 for the three months ended March 31, 2024, and 2023, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of March 31, 2024, and December 31, 2023, the Company had accrued $24,738 and $40,419, respectively, for sales-based, trademark and tiered royalties.

In July 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.

10. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	March 31, 2024	December 31, 2023
Royalties due to Bioprojet	$ 24,738	$ 40,419
Rebates and other sales deductions	48,165	38,842
Interest	3,125	3,354
Sales and marketing	2,999	2,354
Research and development	7,898	9,835
Professional fees, consulting, and other services	1,918	2,195
Other expenses	2,856	2,495
	$ 91,699	$ 99,494

11. DEBT

Term Loan A Credit Agreement

In July 2023, the Company entered into a Credit Agreement (the "TLA Credit Agreement") with JPMorgan Chase Bank, N.A., as "Administrative Agent", and certain lenders. The TLA Credit Agreement provides for a five-year senior secured term loan (the "TLA Term Loan") in an aggregate principal amount of $185,000.

In September 2023, the Company entered into the First Incremental Amendment (the "First Incremental Amendment") with the Administrative Agent and Bank of America, N.A., as incremental lender. The First Incremental Amendment provides for an incremental senior secured term loan (the "Incremental Term Loan") in an aggregate principal amount of $15,000. The First Incremental Amendment amends the TLA Credit Agreement and provides that the Incremental Term Loan will have identical terms as the TLA Term Loan.

The repayment schedule for both the TLA Term Loan and the Incremental Term Loan (together, the "Term Loans") consists of quarterly $3,750 principal payments, which commence on December 31, 2023, increasing to quarterly $5,000 principal payments beginning on December 31, 2025, with a $115,000 payment due on the maturity date of July 26, 2028. The Term Loans bear interest at a per annum rate equal to, at the Company's option, (i) a base rate plus a specified margin ranging from 2.50% to 3.00%, based on the Company's senior secured net leverage ratio (as defined in the TLA Credit Agreement) or (ii) Term SOFR plus a credit spread adjustment of 0.10% plus a specified margin ranging from 3.50% to 4.00%, based on the Company's senior secured net leverage ratio.

The net cash received related to the Term Loans as a result of the transactions, less debt issuance costs of $2,997, was $197,003. The debt issuance costs related to the Term Loans will be amortized as additional interest expense over the loan term of the TLA Credit Agreement. The fair value of the Term Loans as of March 31, 2024, was $192,267.

Long-term debt, net consists of the following:

	March 31, 2024	December 31, 2023
Principal amount	$ 192,500	$ 196,250
Unamortized debt discount associated with debt financing costs	(2,504)	(2,684)
Total debt, net	189,996	193,566
Less current portion	(15,000)	(15,000)
Long-term debt, net	$ 174,996	$ 178,566

Future minimum payments relating to total debt, net as of March 31, 2024, for the periods indicated below consists of the following:

Years ending December 31,	
2024 (excluding the three months ended March 31, 2024)	$ 11,250
2025	16,250
2026	20,000
2027	20,000
2028	125,000
Thereafter	—
Total	$ 192,500

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

	Three Months Ended March 31,	
	2024	2023
Interest on principal balance	$ 4,355	$ 5,315
Amortization of deferred financing costs	180	416
Total term loan interest expense	$ 4,535	$ 5,731

12. 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 into 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. In March 2024, the Company amended its existing operating leases for office space in Plymouth Meeting to extend their terms through June 2025. 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 $509 and $378 for the three months ended March 31, 2024, and 2023, respectively.

As of March 31, 2024, the weighted-average remaining lease term for operating leases was 1.8 years and the weighted-average discount rate for operating leases was 7.32%.

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

Leases	Classification	March 31, 2024	December 31, 2023
Assets			
Operating lease right-of-use assets	Other noncurrent assets	$ 3,046	$ 2,344
Liabilities			
Operating lease liability, current portion	Other current liabilities	$ 1,793	$ 1,437
Operating lease liability, long-term	Other long-term liabilities	1,276	1,082
Total operating lease liabilities		$ 3,069	$ 2,519

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

	March 31, 2024	March 31, 2023
Operating cash flows from operating leases	$ 561	$ 428
Right of use assets obtained in exchange for operating lease obligations	$ 1,198	$ 526

Future payments under noncancelable operating leases with initial terms of one year or more as of March 31, 2024, consisted of the following:

Years ending December 31,	
2024 (excluding the three months ended March 31, 2024)	$ 1,564
2025	1,239
2026	473
2027	3
2028	-
Thereafter	-
Total lease payments	3,279
Less: imputed interest	(210)
Total lease liabilities	$ 3,069

13. 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, 2024, there were no material claims or suits outstanding.

14. 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 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.

Share Repurchase Program

In October 2023, the Company's Board of Directors approved a share repurchase program (the "October 2023 Repurchase Program") providing for the repurchase of shares of common stock in an aggregate amount of up to $200,000, excluding commissions and transaction fees. The October 2023 Repurchase Program may be suspended, terminated, or modified at any time for any reason. During the three months ended March 31, 2024, and 2023, no shares of common stock were repurchased and cancelled by the Company. As of March 31, 2024 the remaining amount of common stock authorized for repurchases was $150,000.

15. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

2020 Stock Incentive Plan

In August 2020, the Company 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, 2024, there were 7,890,232 shares of common stock available for issuance under the 2020 Plan. The number of shares that may be issued under the 2020 Plan automatically increases 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, 2024:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2023	6,316,422	$ 32.47	7.17
Awards issued	1,071,750	$ 30.69	
Awards exercised	(14,120)	$ 8.22	
Awards forfeited	(11,529)	$ 39.31	
Awards outstanding—March 31, 2024	7,362,523	$ 32.25	7.35

Stock Appreciation Rights

The following table summarizes SARs activity for the three months ended March 31, 2024:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2023	43,208	$ 9.38	5.32
Awards issued	—	$ —	
Awards exercised	—	$ —	
Awards forfeited	—	$ —	
Awards outstanding—March 31, 2024	43,208	$ 9.38	5.08

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2024:

	Number of Awards	Weighted-Average Grant Date Fair Value
Awards outstanding—December 31, 2023	330,000	$ 31.53
Awards issued	387,500	$ 30.69
Awards vested	(15,000)	$ 29.03
Awards forfeited	(350)	$ 30.69
Awards outstanding—March 31, 2024	702,150	$ 31.08

As of March 31, 2024, and December 31, 2023, stock awards issued under the 2017 and 2020 Plans of 3,596,040 and 3,298,284 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, 2024	December 31, 2023
Dividend yield	0.00 %	0.00 %
Expected volatility	72.60 - 72.60 %	74.87 - 80.78 %
Risk-free interest rate	4.06 - 4.20 %	3.42 - 4.62 %
Lack of marketability discount	0.00 %	0.00 %
Expected term (years)	2.01 - 6.11	2.26 - 10.77

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 $21.13 and $20.64 on March 31, 2024, and December 31, 2023, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense for the three months ended March 31, 2024, and 2023, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income in the following line items:

	Three Months Ended March 31,	
	2024	2023
Research and development expense	$ 1,371	$ 976
Sales and marketing expense	1,994	1,073
General and administrative expense	7,069	4,512
	$ 10,434	$ 6,561

Stock-based compensation expense 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, 2024, the total unrecognized stock-based compensation expense was $73,718 and $19,399 for stock options and RSUs, respectively. This amount will be recognized in the Company's consolidated statement of operations over a weighted average period of 2.7 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 automatically increases 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 the three months ended March 31, 2024, and 2023, respectively. The discount on the ESPP was $80 and $105 for the three months ended March 31, 2024, and 2023, respectively, and is recorded within stock-based compensation expense.

16. 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 share of common 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,	
	2024	2023
Numerator		
Net income	$ 38,334	$ 29,485
Denominator		
Net income per share of common stock - basic	$ 0.68	$ 0.49
Net income per share of common stock- diluted	$ 0.67	$ 0.48
Weighted average number of shares of common stock - basic	56,771,251	59,732,157
Weighted average number of shares of common stock - diluted	57,597,627	61,221,511

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

	Three Months Ended March 31,	
	2024	2023
Stock options, SARs, and RSUs to purchase common stock	826,376	1,489,354

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,	
	2024	2023
Stock options, SARs, and RSUs to purchase common stock	7,281,505	4,661,499

17. INCOME TAXES

A reconciliation between the statutory federal income tax rate and the Company's effective income tax rate for the three months ended March 31, 2024, and 2023 is as follows:

	Three Months Ended March 31,	
	2024	2023
Federal income tax rate	21.0 %	21.0 %
Stock-based compensation	—	(2.8)
State taxes	5.1	6.3
Credits	(1.0)	(2.9)
Other	0.4	0.4
Valuation allowance	0.5	—
Total	26.0 %	22.0 %

18. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon Biosciences, LLC ("Paragon"). Paragon is an entity that shares common ownership with the Company. In addition, the Chairman of the Company's board of directors is the Founder, Chairman and CEO of Paragon. The Company is also party to a right of use agreement with Paragon whereby it has access to and the right to use certain office space leased by Paragon in Chicago, IL. The Company incurred $73 and $71 for the three months ended March 31, 2024, and 2023, respectively, in expenses to Paragon, which are included in general and administrative expense in the unaudited condensed consolidated statements of operations and comprehensive loss. As of March 31, 2024, and December 31, 2023, there were no amounts due to or due from related parties included in the unaudited condensed consolidated balance sheets.

19. SUBSEQUENT EVENTS

On April 11, 2024, the Company announced that it entered into a sublicense agreement with Bioprojet for an orexin-2 receptor agonist (OX2R) (the "Licensed Compound") to be evaluated for the treatment of narcolepsy and other potential indications (the "Sublicense"). Under the Sublicense, the Company obtained the exclusive right to develop, manufacture and commercialize the Licensed Compound in the United States and Latin American territories (the "Licensed Territories"), which are rights that Bioprojet originally licensed from Teijin Pharma, the innovator of the Licensed Compound. The Licensed Compound is currently in pre-clinical development with an Investigational New Drug application currently anticipated in the second half 2025. Under the Sublicense, the Company paid Bioprojet an upfront license fee of $25,500 and will also be obligated to pay up to $127,500 upon achievement of development and regulatory milestones and up to $240,000 upon achievement of sales-based milestones, as well as royalty rates in the mid-teens on any sales of product using the Licensed Compound in the Licensed Territories.

On April 30, 2024, the Company announced that its subsidiary, Zynerba, acquired all of the issued and outstanding capital stock of Epygenix Therapeutics, Inc., a Wyoming corporation ("Epygenix"), pursuant to the terms of a stock purchase agreement. In connection with the closing of the transaction, Zynerba paid the former stockholders of Epygenix up front consideration of $35,000 (which amount is subject to adjustment following the closing). In addition, Zynerba will also be obligated to pay up to $130,000 upon the achievement of development and regulatory milestones and up to $515,000 upon the achievement of certain sales-based milestones, in each case to Epygenix's former stockholders. Epygenix has an exclusive license relating to the use of clemizole for the treatment of Dravet Syndrome and Lennox-Gestaut Syndrome.

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, acquire and integrate 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 identified idiopathic hypersomnia ("IH"), another central disorder of hypersomnolence like narcolepsy, as our next potential new indication for WAKIX, which received orphan drug designation by the FDA in September 2023 and Fast Track Designation in November 2023. 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 completed enrollment in the INTUNE study in May 2023 and we announced topline data in October 2023. While the primary endpoint did not meet statistical significance, we believe the totality of the data showed favorable numerical trends for pitolisant in the treatment of adult patients with IH and we met with the FDA in March 2024 to discuss the path forward for IH. Following our meeting with the FDA, we plan to submit a supplemental NDA ("sNDA") for IH in the second half of 2024 based on the totality of the data obtained from the INTUNE study and from other sources. 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 positive signals from the data from our Phase 2 proof-of-concept signal detection 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 was held in June 2023. We aligned with the FDA on the proposed Phase 3 registration study design to support further investigation of pitolisant as a potential treatment to address the unmet medical need for children, adolescents and adults with PWS experiencing EDS, for which there is currently no approved treatment. In October 2023, we received FDA alignment regarding the protocol for the Phase 3 TEMPO study in patients with PWS, which we believe will satisfy the requirements for both the registrational trial and one of the two requirements for pediatric exclusivity for pitolisant. In February 2024, the FDA granted Orphan Drug designation to pitolisant for the treatment of PWS. The Phase 3 registrational trial, the TEMPO study, was initiated in March 2024. In June 2021, we initiated a Phase 2 proof-of-concept signal

detection clinical trial to evaluate pitolisant for the treatment of EDS, fatigue and cognitive dysfunction in adult patients with DM1 and announced topline results from this trial in the fourth quarter of 2023, in which clinically meaningful improvements were demonstrated in EDS and fatigue. The safety profile was consistent with the established safety profile of pitolisant.

Our partner, Bioprojet completed a Phase 3 trial in pediatric patients with narcolepsy and submitted the trial data to the European Medicines Agency (the "EMA") seeking approval for a pediatric narcolepsy indication. In January 2023, Bioprojet received a positive opinion from the EMA's Committee for Medicinal Products for Human Use ("CHMP") and in March 2023, the EMA granted approval for the marketing authorization of WAKIX for the treatment of narcolepsy in children 6 and older. Based on the data from the positive Phase 3 trial conducted by Bioprojet, we submitted an sNDA for pediatric narcolepsy in December 2023. On February 21, 2024, we announced that the FDA has granted priority review of our pediatric narcolepsy sNDA and has set a Prescription Drug User Fee Act, or target action date, of June 21, 2024.

We remain committed to obtaining pediatric exclusivity for WAKIX. The initiation of the PWS Phase 3 registrational trial, the TEMPO study, and pediatric narcolepsy sNDA are supportive of our efforts in obtaining 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, develop 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 have made progress in the development of two new formulations of pitolisant, Next Gen 1 ("NG1") and Next Gen 2 ("NG2"). Both formulations entered clinical studies in the fourth quarter of 2023. We received data from the NG1 pilot bioequivalence study, which supports further development of NG1. We anticipate data from the NG2 pilot pharmacokinetics study in the second half of 2024. These formulations are expected to generate new IP to extend the pitolisant franchise out beyond 2040.

In addition, in October 2023, we completed the acquisition of Zynerba Pharmaceuticals, Inc. (together with its subsidiary, Zynerba Pharmaceutical Pty, Ltd., "Zynerba"), a clinical-stage pharmaceutical company focused on innovative pharmaceutically produced transdermal cannabidiol therapies for orphan neuropsychiatric disorders. Zynerba's drug candidate is ZYN002, the first and only pharmaceutically-produced synthetic cannabidiol gel, devoid of THC, and formulated as a patent protected, permeation-enhanced gel for transdermal delivery. ZYN002 is currently in a pivotal Phase 3 trial, the RECONNECT study, for the treatment of Fragile X Syndrome ("FXS"). Topline data from this Phase 3 study is anticipated in mid-2025. ZYN002 has patent protection for the treatment of FXS until 2038.

In August 2021, we acquired HBS-102, a Melanin-concentrating hormone receptor 1 (MCHR1) antagonist previously developed as CSTI-100/ALB-127258(a)/ALB-127258 (the "Compound"), along with intellectual property and other assets related to the development, manufacture, and commercialization of the Compound from ConSynance Therapeutics, Inc. We acquired full development and commercialization rights for HBS-102 globally, but we have provided an indication-limited grant-back license to ConSynance for the development and commercialization of the Compound in Greater China. We are conducting 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. We anticipate data from both studies in the first half of 2024. A 13-week toxicology study is completed and the preliminary results are encouraging.

In April 2024, we entered into a sublicense agreement with Bioprojet for an orexin-2 receptor agonist (OX2R) (the "Licensed Compound") to be evaluated for the treatment of narcolepsy and other potential indications (the "Sublicense"). Under the Sublicense, the Company obtained the exclusive right to develop,

manufacture and commercialize the Licensed Compound in the United States and Latin American territories, which are rights that Bioprojet originally licensed from Teijin Pharma, the innovator of the Licensed Compound.

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.

Our operations are conducted by our wholly owned subsidiaries, Harmony Biosciences, LLC and Zynerba.

Commercial Performance Metrics

As of March 31, 2024, 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, 2024, was approximately 6,300. Additionally, as of March 31, 2024, 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

Net Product Revenue

Net product revenue includes gross product shipments less provisions for sales discounts and allowances, which includes trade allowances, rebates to government and commercial entities, and other 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 API, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs and salaries of employees involved with oversight of 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 June 2025. 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 have adequate supply of WAKIX to cover demand into the third quarter of 2025, 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, DM and the development of ZYN002 in patients with FXS. 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 and assess other product candidates to expand our pipeline. Research and development expenses also include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our research and development personnel;
- direct third-party costs such as expenses incurred under agreements with CROs, and contract manufacturing organizations ("CMOs");
- manufacturing costs in connection with producing materials for use in conducting clinical trials;
- costs related to packaging and labelling of clinical supplies;
- other third-party expenses (e.g., consultants, advisors) directly attributable to the development of our product candidates;
- acquired in-process research and development; and
- amortization expense for assets used in research and development activities.

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 in the current period 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, complete the Phase 3 clinical trial for ZYN002, and advance NG1, NG2, ZYN002 and HBS-102 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 Agreement

We are party to a right-of-use agreement with Paragon Biosciences, LLC (“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, 2024, we paid fees of $0.1 million pursuant to this agreement.

Interest Expense

Interest expense consists primarily of interest expense on debt facilities, amortization of debt issuance costs and amortization of premiums on our debt securities.

Interest Income

Interest income consists primarily of cash interest earned on our cash and investment balances and accretion of the discount on our investments in 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,	
	2024	2023
	(In thousands)	
Net product revenue	$ 154,615	$ 119,126
Cost of product sales	27,484	20,780
Gross profit	127,131	98,346
Operating expenses:		
Research and development	22,189	13,289
Sales and marketing	27,233	22,572
General and administrative	25,676	22,062
Total operating expenses	75,098	57,923
Operating income	52,033	40,423
Other (expense) income, net	(141)	2
Interest expense	(4,535)	(5,731)
Interest income	4,428	3,086
Net income before provision for income taxes	51,785	37,780
Income tax (expense) benefit	(13,451)	(8,295)
Net income	$ 38,334	$ 29,485

Net Product Revenue

Net product revenue increased by $35.5 million, or 29.8%, for the three months ended March 31, 2024 compared to the same period in 2023. The increase was primarily due to a 28.3% increase in the number of units shipped, and the impact of a 7% price increase partially offset by higher rebates to commercial entities, which resulted in a decrease to net product revenue of approximately 4%. The price increase occurred in January 2024.

Cost of Product Sales

Cost of product sales increased by $6.7 million, or 32.3%, for the three months ended March 31, 2024, compared to the same period in 2023. Cost of product sales as a percentage of net product revenue was 17.8% for the three months ended March 31, 2024, compared to 17.4% for the three months ended March 31, 2023. The increase in cost of product sales in the period was due to higher sales of WAKIX.

Research and Development Expenses

The following table is a summary of our research and development expenses:

	Three Months Ended March 31,		
	2024	2023	Change
	(in thousands)		
Pitolisant	$ 9,110	$ 6,187	$ 2,923
ZYN002	3,879	-	3,879
Other research and development	2,446	1,774	672
IPR&D	-	750	(750)
Personnel expenses	5,383	3,602	1,781
Stock-based compensation	1,371	976	395
Total	$ 22,189	$ 13,289	$ 8,900

Research and development expenses increased by $8.9 million, or 67.0%, for the three months ended March 31, 2024, compared to the same period in 2023. The increase for the three months ended March 31, 2024 was primarily driven by $3.9 million in research and development expenses for ZYN002, which did not have any expenses in the prior year, a $2.9 million increase in clinical development and regulatory work associated with pitolisant, driven by increases for PWS and DM indications, a $1.8 million increase in personnel costs associated with higher headcount and a $0.4 million increase in stock compensation associated with new awards, partially offset by a $0.8 million IPR&D charge related to preclinical milestones achieved for HBS-102 during the three months ended March 31, 2023.

Sales and Marketing Expenses

Sales and marketing expenses increased by $4.7 million, or 20.6%, for the three months ended March 31, 2024, compared to the same period in 2023. The increase for the three months ended March 31, 2024, was primarily due to a $2.7 million increase in patient engagement and marketing activities, a $0.9 million increase in personnel costs, and a $0.9 million increase in stock compensation associated with new awards. The increase in patient engagement and marketing activities for the period was driven by our continued growth of WAKIX and the increase in personnel costs for the period was related to increased headcount.

General and Administrative Expenses

General and administrative expenses increased by $3.6 million, or 16.4%, for the three months ended March 31, 2024, compared to the same period in 2023. The increase in the three months ended March 31, 2024, was primarily due to a $2.6 million increase in stock compensation associated with new awards and a $0.8 million increase in legal fees, primarily associated with patent lawsuits.

Interest Expense

Interest expense decreased by $1.2 million, or 20.9%, for the three months ended March 31, 2024, compared to the same period in 2023. The decrease for the three months ended March 31, 2024, was primarily due to lower interest rates as a result of refinancing into the TLA Credit Agreement (defined below).

Interest Income

Interest income increased by $1.3 million, or 43.5%, for the three months ended March 31, 2024, compared to the same period in 2023. The increase for the three months ended March 31, 2024, was primarily a result of having higher invested balances, and higher investment yields on those balances, compared to the prior year period.

Income Taxes

Income tax expense was $13.5 million, representing a 26.0% effective tax rate, for the three months ended March 31, 2024, compared to $8.3 million, representing a 22.0% effective tax rate, for the three months ended March 31, 2023. The increase in our effective tax rate was due to a 2.8% tax benefit from the exercise of stock options in the prior year period and a 1.9% benefit from estimated tax credits. The effective tax rate of 26.0% for the three months ended March 31, 2024, included 5.1% for state income taxes, partially offset by a 1.0% benefit from credits.

Liquidity, Sources of Funding and Capital Resources

Overview

As of March 31, 2024, we had cash, cash equivalents, and investments of $453.6 million, outstanding debt of $192.5 million and an accumulated deficit of $104.9 million.

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

We believe that our existing cash, cash equivalents and investments on hand as of March 31, 2024, 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.

Term Loan A Credit Agreement

In July 2023, we entered into a Credit Agreement (the "TLA Credit Agreement") with JPMorgan Chase Bank, N.A., as "Administrative Agent", and certain lenders. The TLA Credit Agreement provides for a five-year senior secured term loan (the "TLA Term Loan") in an aggregate principal amount of $185.0 million.

In September 2023, we entered into the First Incremental Amendment (the "First Incremental Amendment") with the Administrative Agent and Bank of America, N.A., as incremental lender. The First Incremental Amendment provides for an incremental senior secured term loan (the "Incremental Term Loan") in an aggregate principal amount of $15.0 million. The First Incremental Amendment amends the TLA Credit Agreement and provides that the Incremental Term Loan will have identical terms as the TLA Term Loan.

The repayment schedule for both the TLA Term Loan and the Incremental Term Loan (together, the "Term Loans") consists of $3.8 million quarterly principal payments, which commence on December 31, 2023, increasing to $5.0 million quarterly principal payments beginning on December 31, 2025, with a $115.0 million payment due on the maturity date of July 26, 2028. The Term Loans bear interest at a per annum rate equal to, at our option, (i) a base rate plus a specified margin ranging from 2.50% to 3.00%, based on our senior secured net leverage ratio (as defined in the TLA Credit Agreement) or (ii) Term SOFR plus a credit spread adjustment of 0.10% plus a specified margin ranging from 3.50% to 4.00%, based on our senior secured net leverage ratio.

The TLA Credit Agreement contains customary affirmative and negative covenants, financial covenants, representations and warranties, events of default and other provisions. We were in compliance with all covenants as of March 31, 2024.

Share Repurchases

In October 2023, the Company's Board of Directors approved a share repurchase program (the "October 2023 Repurchase Program") providing for the repurchase of shares of common stock in an aggregate amount of up to $200,000, excluding commissions and transaction fees. The October 2023 Repurchase Program may be suspended, terminated, or modified at any time for any reason. During the three months ended March 31, 2024, the Company repurchased and cancelled no shares of common under the October 2023 Repurchase Program. As of March 31, 2024, the remaining amount of common stock authorized for repurchases was $150.0 million.

Zynerba Acquisition

In October 2023, we completed a tender offer (the "Tender Offer") to acquire all of the outstanding shares of common stock of Zynerba ("Zynerba Common Stock").

Under the terms of the Tender Offer, we paid (i) $1.1059 per share of Zynerba Common Stock (the "Common Cash Amount"), the aggregate amount of which was $60,000 and was paid at closing, plus (ii) one contingent value right (each, a "CVR") per share of Zynerba Common Stock (the "Common CVR Amount"), which represents the right to receive up to approximately $2.5444 per share of Zynerba Common Stock, subject to the achievement of certain clinical, regulatory and sales-based milestones. The Common CVR Amounts are to be paid in cash, subject to any applicable withholding of taxes and without interest. The aggregate consideration we paid to acquire the Zynerba Common Stock upon completion of the Tender Offer was $60 million, exclusive of transaction related fees. We financed the acquisition with cash on hand.

Asset Purchase Agreement

In August 2021, we entered into an asset purchase agreement with ConSynance Therapeutics, Inc. (the (APA") to acquire HBS-102, a potential first-in-class molecule with a novel mechanism of action. Under the terms of the APA, 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 below, including $1.0 million for additional preclinical milestones (see "Recent Milestone Payments"), $19.0 million for development milestones, $44.0 million for regulatory milestones and $110.0 million for sales milestones.

License Agreements

In April 2024, we entered into a sublicense agreement with Bioprojet for an orexin-2 receptor agonist (OX2R) (the "Licensed Compound") to be evaluated for the treatment of narcolepsy and other potential indications (the "Sublicense"). Under the Sublicense, the Company obtained the exclusive right to develop, manufacture and commercialize the Licensed Compound in the United States and Latin American territories (the "Licensed Territories"), which are rights that Bioprojet originally licensed from Teijin Pharma, the innovator of the Licensed Compound. The Licensed Compound is currently in pre-clinical development with an Investigational New Drug application currently anticipated in the second half 2025. Under the Sublicense, the Company will pay Bioprojet an upfront license fee of $25.5 million and will also be obligated to pay up to $127.5 million upon achievement of development and regulatory milestones and up to $240.0 million upon achievement of sales-based milestones, as well as royalty rates in the mid-teens on potential sales in the Licensed Territories.

In July 2022, we entered into the 2022 LCA with Bioprojet whereby we obtained exclusive rights to manufacture, develop 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 was paid in April 2023.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2024, and 2023:

	Three Months Ended March 31,	
	2024	2023
Selected cash flow data	(In thousands)	
Cash provided by (used in):		
Operating activities	$ 31,141	$ 42,559
Investing activities	(6,186)	(1,790)
Financing activities	(3,634)	3,409

Operating Activities

Net cash provided by operating activities for the three months ended March 31, 2024, primarily consisted of net income of $38.3 million adjusted for non-cash items of $10.4 million related to stock-based compensation expense, $6.1 million related to intangible amortization and depreciation, and $3.5 million related to deferred tax assets. Net working capital excluding cash decreased by $20.3 million.

Net cash provided by operating activities of $42.6 million for the three months ended March 31, 2023, consisted of 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.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024, was $6.2 million, which was primarily attributable to $25.1 million in purchases of debt securities, partially offset by $18.9 million from maturities of investments.

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 from sales and maturities of investments.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2024, was $3.6 million, which primarily consisted of $3.7 million in principal payments associated with the TLA Credit Agreement, partially offset by $0.1 million in proceeds from the exercise of stock options.

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 the exercise of stock options partially offset by a $0.5 million principal payment 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, 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 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 $384.7 million of investments in money market funds, U.S. treasury notes, corporate bonds and municipal obligations as of March 31, 2024, 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, 2024, we had $192.5 million in borrowings outstanding. The Term Loans bear interest at a per annum rate equal to, at our option, (i) a base rate plus a specified margin ranging from 2.50% to 3.00%, based on our senior secured net leverage ratio (as defined in the TLA Credit Agreement) or (ii) Term SOFR plus a credit spread adjustment of 0.10% plus a specified margin ranging from 3.50% to 4.00%, based on our senior secured net leverage ratio. Based on the $192.5 million of principal outstanding as of March 31, 2024, an immediate 10% change in the SOFR 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 each of the three months ended March 31, 2024, and 2023.

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, 2024. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2024, 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, 2024, 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.

ANDA Litigation

On September 27, 2023, we and our licensor, Bioprojet, received notice from Lupin Limited ("Lupin") pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the "Lupin Notice Letter") that Lupin has submitted ANDA No. 218846 (the "Lupin ANDA") to the FDA and is seeking regulatory approval to market a generic version of WAKIX® before the expiration of U.S. Patent Nos. 8,486,947 ("'947 patent") and 8,207,197 ("'197 patent"). On September 27, 2023, we and Bioprojet received notice from Novugen Pharma Sdn. Bhd. ("Novugen") pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the "Novugen Notice Letter") that Novugen has submitted ANDA No. 218834 (the "Novugen ANDA") to the FDA and is seeking regulatory

approval to market a generic version of WAKIX® before the expiration of the ’947 patent and ’197 patent. The ’947 patent and the ‘197 patent are listed with respect to WAKIX® in the FDA’s Orange Book and will expire in September 2029 and March 2030, respectively. The Lupin Notice Letter and the Novugen Notice Letter assert that their generic product will not infringe the ’947 patent and the ‘197 patent and/or that the ’947 patent and the ‘197 patent are invalid or unenforceable. On November 9, 2023, we, Bioprojet and Bioprojet’s wholly owned subsidiary, Bioprojet Pharma SAS (“Bioprojet Pharma”), filed a complaint for patent infringement of the ’947 patent and the ‘197 patent against Lupin, Novugen and certain of their affiliates and agents in the United States District Court for the District of Delaware in response to the filing of their respective ANDAs with the FDA.

On October 12, 2023, we and Bioprojet received notice from Novitium Pharma LLC (“Novitium”), pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the “Novitium Notice Letter”), that Novitium has submitted ANDA No. 218495 (the “Novitium ANDA”) to the FDA and is seeking regulatory approval to market a generic version of WAKIX® before the expiration of U.S. Patent No. 8,354,430 (the “‘430 patent”), which is also listed with respect to WAKIX® in the FDA’s Orange Book and will expire in February 2026, ’947 patent, and ’197 patent. On October 12, 2023, we and Bioprojet received notice from Zenara Pharma Pvt. Ltd. (“Zenara”), pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the “Zenara Notice Letter”), that Zenara has submitted ANDA No. 218796 (the “Zenara ANDA”) to the FDA and is seeking regulatory approval to market a generic version of WAKIX® before the expiration of the ’430 patent, ’947 patent and the ’197 patent. On October 14, 2023, we and Bioprojet received notice from AET Pharma US, Inc. (“AET”), pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the “AET Notice Letter”), that AET has submitted ANDA No. 218892 (the “AET ANDA”) to the FDA and is seeking regulatory approval to market a generic version of WAKIX® before the expiration of the ’947 patent and the ’197 patent. On October 16, 2023, we and Bioprojet received notice from Annora Pharma Private Limited (“Annora”), pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the “Annora Notice Letter”), that Annora has submitted ANDA No. 218832 (the “Annora ANDA”) to the FDA and is seeking regulatory approval to market a generic version of WAKIX® before the expiration of the ’430 patent, the ’947 patent and the ’197 patent. AET’s Notice Letter asserts that AET’s generic product will not infringe the ’947 patent and the ‘197 patent and/or that ’947 patent and the ‘197 patent are invalid or unenforceable. The Annora Notice Letter asserts that its generic product will not infringe the ‘430 patent, ’947 patent and the ‘197 patent and/or that the ‘430 patent, ’947 patent and the ‘197 patent are invalid or unenforceable. The Novitium Notice Letter asserts that its generic product will not infringe the ‘430 patent, ’947 patent and the ‘197 patent and/or that the ‘430 patent, ’947 patent and the ‘197 patent are invalid or unenforceable. The Zenara Notice Letter asserts that its generic product will not infringe the ‘430 patent, ’947 patent and the ‘197 patent and/or that the ‘430 patent, ’947 patent and the ‘197 patent are invalid or unenforceable. On November 21, 2023, we, Bioprojet and Bioprojet Pharma filed a complaint for patent infringement of the ’947 patent and the ‘197 patent against AET, Annora, Novitium and Zenara and certain of their affiliates and agents and for patent infringement of the ’430 patent against Annora, Novitium and Zenara and certain of their affiliates and agents in the United States District Court for the District of Delaware in response to their filing of their respective ANDAs with the FDA.

In October 2023, MSN Pharmaceuticals Inc. (“MSN Pharma”) sent correspondence to us and Bioprojet stating that MSN Pharma has submitted ANDA No. 218873 (the “MSN ANDA”) to the FDA and is seeking regulatory approval to market a generic version of WAKIX®. On December 8, 2023, MSN Laboratories Private Limited (“MSN”) filed a declaratory judgment action in the United States District Court for the Eastern District of Virginia against Bioprojet claiming that the ‘430 patent, the ’947 patent and the ‘197 patent will not be infringed by MSN’s generic version of WAKIX® and that the ‘947 patent is invalid. On December 11, 2023, we, Bioprojet and Bioprojet Pharma filed a complaint in the United States District Court for the District of Delaware for patent infringement of the ‘430 patent, the ’947 patent and the‘197 patent against MSN and MSN Pharma. On January 12, 2024, the declaratory judgment action was transferred from the United States District Court for the Eastern District of Virginia to the United States District Court for the District of Delaware.

On April 15, 2024, the United States District Court for the District of Delaware issued a scheduling order consolidating the cases described above for all purposes up to and including trial (the “Scheduling Order”). The Scheduling Order set March 27, 2025 as the date for the hearing on claim construction and scheduled a four-day bench trial beginning on February 17, 2026.

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, 2023, 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.

Rule 10b5-1 Trading Arrangements

On February 23, 2024, Jeffrey Dierks, Chief Commercial Officer of the Company, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 35,708 shares of the Company's common stock related to the exercise of options beginning on July 1, 2024 and until December 31, 2024.

During the three months ended March 31, 2024, no director or officer of the Company terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Epygenix Acquisition

On April 30, 2024, the Company announced that its subsidiary Zynerba Pharmaceuticals, Inc. ("Zynerba") acquired all of the issued and outstanding capital stock of Epygenix Therapeutics, Inc., a Wyoming corporation ("Epygenix"), pursuant to the terms of a stock purchase agreement. In connection with the closing of the transaction, Zynerba paid the former stockholders of Epygenix up front consideration of $35 million (which amount is subject to adjustment following the closing). In addition, Zynerba will also be obligated to pay up to $130 million upon the achievement of development and regulatory milestones and up to $515 million upon the achievement of certain sales-based milestones, in each case to Epygenix's former stockholders. Epygenix has an exclusive license relating to the use of clemizole for the treatment of Dravet Syndrome and Lennox-Gestaut Syndrome.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
2.1+	Agreement and Plan of Merger, dated August 14, 2023, by and among Harmony Biosciences Holdings, Inc., Xylophone Acquisition Corp. and Zynerba Pharmaceuticals, Inc.	8-K/A	September 14, 2023	2.1
3.1	Amended and Restated Certificate of Incorporation of Harmony Biosciences Holdings, Inc.	8-K	August 21, 2020	3.1
3.2	Amended and Restated Bylaws.	8-K	August 21, 2020	3.2
10.1*	Amendment No. 1 to License and Commercialization Agreement, dated July 31, 2022, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.			
10.2*	Amendment No. 2 to License and Commercialization Agreement, dated July 28, 2017, by and between Bioprojet Société Civile de Recherche and Harmony Biosciences, LLC.			
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 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.

\+ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 for any schedules so furnished.

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: April 30, 2024

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer and Chief Administrative Officer (principal financial officer)
Date: April 30, 2024

AMENDMENT NO. 1

TO

LICENSE AND COMMERCIALIZATION AGREEMENT

This Amendment No. 1, dated as of April 6, 2024 (this "First Amendment"), to the License and Commercialization Agreement, dated as of July 31, 2022, (the "Agreement"), is entered into between Bioprojet Société Civile de Recherche, an independent (privately) owned research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France (together with its Affiliates, including Bioprojet Pharma SAS and Bioprojet Europe Ltd., "Bioprojet"), and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania 19462 USA ("Partner"). Capitalized terms used, but not otherwise defined, in this First Amendment shall have the meanings ascribed to them in the Agreement. Bioprojet and Partner may be referred to herein, together, as the "Parties" and, individually, as a "Party."

WHEREAS, the Parties have previously entered into the Agreement;

WHEREAS, the Parties have agreed to expand their collaboration by entering into a co-development agreement with respect to an orexin program in-licensed from Teijin; and

WHEREAS, in accordance with the Agreement, the Parties desire to further amend the Agreement, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the adequacy and receipt of which hereby are acknowledged, the Parties hereby agree as follows:

1. The Parties hereby agree that Section 1.41 ("Field Products") of the Agreement is hereby deleted in its entirety.

2. The Parties hereby agree that Section 8.3 ("Exclusivity of Efforts - Harmony") of the Agreement is hereby deleted in its entirety.

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

4. Except as otherwise provided herein, the Agreement shall remain unchanged and in full force and effect.

5. From and after the execution of this First Amendment by the Parties, any reference to the Agreement shall be deemed to be a reference to the Agreement as amended by this First Amendment.

6. The provisions of Article 19 and Sections 20.2 to 20.13 of the Agreement apply to this First Amendment mutatis mutandis, except that in accordance with paragraph 5 above references to "Agreement" shall be read as references to this First Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this First Amendment as of the day and year first written above.

BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE

By: /s/ Jeanne-Marie Lecomte
Name: Jeanne-Marie Lecomte
Title: Chairman

HARMONY BIOSCIENCES, LLC

By: /s/ Jeffrey M Dayno, MD
Name: Jeffrey M Dayno, MD
Title: President & Chief Executive Officer

AMENDMENT NO. 2

TO

LICENSE AND COMMERCIALIZATION AGREEMENT

This Amendment No. 2, dated as of April 6, 2024 (this "Second Amendment"), to the License and Commercialization Agreement, dated as of July 28, 2017, and amended on August 27, 2018 (the "First Amendment", collectively the "Agreement"), is entered into between Bioprojet Société Civile de Recherche, an independent (privately) owned research company organized under the laws of France and having its principal place of business at 30, rue des Francs-Bourgeois, 75003 Paris, France ("Bioprojet SCR") and together with its Affiliates, including Bioprojet Pharma SARL and Bioprojet Europe Ltd., "Bioprojet"), and Harmony Biosciences, LLC, a limited liability company organized under the laws of Delaware and having its principal place of business at 630 W. Germantown Pike, Suite 215, Plymouth Meeting, Pennsylvania 19462 USA ("Partner"). Capitalized terms used, but not otherwise defined, in this Second Amendment shall have the meanings ascribed to them in the Agreement. Bioprojet and Partner may be referred to herein, together, as the "Parties" and, individually, as a "Party."

WHEREAS, the Parties have previously entered into the Agreement and the First Amendment;

WHEREAS, the Parties have agreed to expand their collaboration by entering into a co-development agreement with respect to an orexin program in-licensed from Teijin; and

WHEREAS, in accordance with the Agreement, the Parties desire to further amend the Agreement, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the adequacy and receipt of which hereby are acknowledged, the Parties hereby agree as follows:

1. The Parties hereby agree that Section 1.20 ("Field Products") of the Agreement is hereby deleted in its entirety.

2. The Parties hereby agree that Section 8.3 ("Exclusivity of Efforts") of the Agreement is hereby deleted in its entirety.

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

4. Except as otherwise provided herein, the Agreement shall remain unchanged and in full force and effect.

5. From and after the execution of this Second Amendment by the Parties, any reference to the Agreement shall be deemed to be a reference to the Agreement as amended by this Second Amendment.

6. The provisions of Article 19 and Sections 20.2 to 20.8, 20.10 and 20.11 of the Agreement apply to this Second Amendment mutatis mutandis, except that in accordance with paragraph 5 above references to "Agreement" shall be read as references to this Second Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this Second Amendment as of the day and year first written above.

BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE

By: /s/ Jeanne-Marie Lecomte
Name: Jeanne-Marie Lecomte
Title: Chairman

HARMONY BIOSCIENCES, LLC

By: /s/ Jeffrey M Dayno, MD
Name: Jeffrey M Dayno, MD
Title: President & Chief Executive Officer

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: April 30, 2024

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: April 30, 2024

By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer and Chief Administrative 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, 2024, 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: April 30, 2024

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, 2024 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: April 30, 2024

By: /s/ Sandip Kapadia

Sandip Kapadia
Chief Financial Officer and Chief Administrative 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.