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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2025
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
(State or other jurisdiction of
incorporation or organization)

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

630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA
(Address of principal executive offices)

19462
(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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 31, 2025, there were 57,596,358 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)

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 646,999	\$ 453,001
Investments, short-term	25,582	14,185
Trade receivables, net	100,651	83,033
Inventory, net	6,882	7,198
Prepaid expenses	23,308	13,714
Other current assets	35,378	8,121
Total current assets	<u>838,800</u>	<u>579,252</u>
NONCURRENT ASSETS:		
Property and equipment, net	1,440	1,257
Investments, long-term	105,831	108,874
Intangible assets, net	95,380	113,263
Deferred tax asset	157,075	190,398
Other noncurrent assets	9,692	6,156
Total noncurrent assets	<u>369,418</u>	<u>419,948</u>
TOTAL ASSETS	\$ 1,208,218	\$ 999,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 26,341	\$ 13,744
Accrued compensation	14,935	18,776
Accrued expenses	161,302	120,640
Current portion of long-term debt	20,000	16,250
Other current liabilities	825	5,672
Total current liabilities	<u>223,403</u>	<u>175,082</u>
NONCURRENT LIABILITIES:		
Long-term debt, net	148,506	163,016
Other noncurrent liabilities	1,186	1,947
Total noncurrent liabilities	<u>149,692</u>	<u>164,963</u>
TOTAL LIABILITIES	373,095	340,045
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—\$0.00001 par value; 500,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; 57,596,358 and 57,144,887 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	1	1
Additional paid in capital	696,348	656,872
Accumulated other comprehensive income	357	66
Retained earnings	138,417	2,216
TOTAL STOCKHOLDERS' EQUITY	835,123	659,155
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,208,218	\$ 999,200

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)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Net product revenue	\$ 239,455	\$ 186,038	\$ 624,677	\$ 513,467
Cost of product sold	59,650	42,778	129,797	102,406
Gross profit	179,805	143,260	494,880	411,061
Operating expenses:				
Research and development	54,962	25,387	139,661	111,159
Sales and marketing	29,549	27,576	90,333	83,316
General and administrative	29,807	28,587	94,974	81,487
Total operating expenses	114,318	81,550	324,968	275,962
Operating income	65,487	61,710	169,912	135,099
Other expense, net	(106)	(124)	(575)	(228)
Interest expense	(3,621)	(4,348)	(11,103)	(13,287)
Interest income	5,730	4,932	16,070	14,065
Income before income taxes	67,490	62,170	174,304	135,649
Income tax expense	(16,625)	(16,077)	(38,103)	(39,631)
Net income	\$ 50,865	\$ 46,093	\$ 136,201	\$ 96,018
Unrealized income on investments	118	733	291	497
Comprehensive income	\$ 50,983	\$ 46,826	\$ 136,492	\$ 96,515
EARNINGS PER SHARE:				
Basic	\$ 0.88	\$ 0.81	\$ 2.36	\$ 1.69
Diluted	\$ 0.87	\$ 0.79	\$ 2.32	\$ 1.66
Weighted average number of shares of common stock - basic	57,550,902	56,870,234	57,655,272	56,815,167
Weighted average number of shares of common stock - diluted	58,717,910	58,103,963	58,738,361	57,754,016

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	Retained earnings	Total stockholders' equity
	Shares	Amount				
Balance as of June 30, 2025	57,531,080	\$ 1	\$ 685,288	\$ 239	\$ 87,552	\$ 773,080
Net income	—	—	—	—	50,865	50,865
Unrealized loss on investments	—	—	—	118	—	118
Exercise of options	65,278	—	91	—	—	91
Stock-based compensation	—	—	10,969	—	—	10,969
Balance as of September 30, 2025	<u>57,596,358</u>	<u>\$ 1</u>	<u>\$ 696,348</u>	<u>\$ 357</u>	<u>\$ 138,417</u>	<u>\$ 835,123</u>

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Retained earnings	Total stockholders' equity
	Shares	Amount				
Balance as of December 31, 2024	57,144,887	\$ 1	\$ 656,872	\$ 66	\$ 2,216	\$ 659,155
Net income	—	—	—	—	136,201	136,201
Unrealized gain on investments	—	—	—	291	—	291
Exercise of options and restricted stock units	451,471	—	4,553	—	—	4,553
Stock-based compensation	—	—	34,923	—	—	34,923
Balance as of September 30, 2025	<u>57,596,358</u>	<u>\$ 1</u>	<u>\$ 696,348</u>	<u>\$ 357</u>	<u>\$ 138,417</u>	<u>\$ 835,123</u>

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance as of June 30, 2024	56,833,771	\$ 1	\$ 632,168	\$ (234)	\$ (93,352)	\$ 538,583
Net income	—	—	—	—	46,093	46,093
Unrealized loss on investments	—	—	—	733	—	733
Exercise of options	197,126	—	347	—	—	347
Stock-based compensation	—	—	11,048	—	—	11,048
Balance as of September 30, 2024	<u>57,030,897</u>	<u>\$ 1</u>	<u>\$ 643,563</u>	<u>\$ 499</u>	<u>\$ (47,259)</u>	<u>\$ 596,804</u>

	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	—	—	—	—	96,018	96,018
Unrealized loss on investments	—	—	—	497	—	497
Exercise of stock options and restricted stock units	261,816	—	767	—	—	767
Stock-based compensation	—	—	32,530	—	—	32,530
Balance as of September 30, 2024	<u>57,030,897</u>	<u>\$ 1</u>	<u>\$ 643,563</u>	<u>\$ 499</u>	<u>\$ (47,259)</u>	<u>\$ 596,804</u>

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)

	Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 136,201	\$ 96,018
<i>Adjustments to reconcile net income to net cash used in operating activities:</i>		
Depreciation	20	261
Intangible amortization	17,883	17,883
Acquired in-process research & development (IPR&D) expense	30,000	42,595
Stock-based compensation	34,923	32,530
Stock appreciation rights market adjustment	(255)	315
Debt issuance costs amortization	490	531
Deferred taxes	(14,677)	(22,586)
Amortization of premiums and accretion of discounts on Investment securities	(1,240)	(1,770)
Other non-cash expenses	923	1,619
<i>Change in operating assets and liabilities:</i>		
Trade receivables	(17,618)	(7,362)
Inventory	316	(1,552)
Prepaid expenses and other assets	6,942	(4,851)
Trade payables	12,597	(8,596)
Other liabilities	15,543	(776)
Net cash provided by operating activities	<u>222,048</u>	<u>144,259</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investment securities	(67,313)	(69,604)
Proceeds from maturities and sales of investment securities	60,500	68,516
Purchase of property and equipment	(203)	(640)
Acquisition of Epygenix Therapeutics, Inc., net of cash acquired	—	(33,069)
Payment of upfront fee related to research collaboration, option and license agreement	(15,000)	(25,500)
Net cash used in investing activities	<u>(22,016)</u>	<u>(60,297)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal repayment of long-term debt	(11,250)	(11,250)
Payments of employee withholding taxes related to stock-based awards	(2,341)	(269)
Proceeds from exercised options	7,557	3,264
Net cash used in financing activities	<u>(6,034)</u>	<u>(8,255)</u>
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	<u>193,998</u>	<u>75,707</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	453,271	311,930
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	<u>\$ 647,269</u>	<u>\$ 387,637</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	\$ 11,168	\$ 13,170
Cash paid during the year for taxes	35,430	58,549

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 subsidiaries, Harmony Biosciences, LLC (“Harmony”), and Harmony Biosciences Management, Inc. The Company is headquartered in Plymouth Meeting, Pennsylvania.

We are cultivating a differentiated neuroscience company, rooted in innovation and driven by a commitment to addressing the unmet needs of patients living with neurological diseases. To date, we have focused on rare neurological diseases with a growing portfolio now spanning sleep/wake, neurobehavioral, and rare epilepsy, and we are harnessing scientific insights and pioneering approaches to advance meaningful treatments that help patients thrive.

In July 2017, the Company entered into a License Agreement (the “2017 LCA”) with Bioprojet Société Civile de Recherche (“Bioprojet”) whereby the Company acquired the exclusive right to commercialize the pharmaceutical compound pitolisant. Our lead product, WAKIX® (pitolisant) (“WAKIX”), is a first-in-class therapy with a novel mechanism of action designed to enhance histamine signaling in the brain by binding to H₃ receptors. Since its initial FDA approval in 2019 for excessive daytime sleepiness (“EDS”) in adult patients with narcolepsy, WAKIX has subsequently been approved for cataplexy in adult patients in 2020 and EDS in pediatric patients six years and older in 2024. Beyond narcolepsy, we are also advancing late-stage clinical programs exploring pitolisant in Prader-Willi syndrome (“PWS”) and continue to grow our impact in other rare neurological diseases. In July 2022, the Company 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 next generation pitolisant based products in the United States and Latin America. Two of the next generations formulations, Pitolisant Gastro-Resistant (“Pitolisant GR”) and Pitolisant High-Dose (“Pitolisant HD”) are currently in clinical development.

Along with nurturing the growth of our original pipeline, our innovation strategy includes targeted business development that strengthens our foundation and strategically extends our patient reach as we look to expand our portfolio to new diseases beyond histaminergic science. In October 2023, the Company acquired Zynerba Pharmaceuticals, Inc. (together with its subsidiary, Zynerba Pharmaceutical Pty, Ltd., “Zynerba”). Zynerba was a clinical-stage pharmaceutical company focused on innovative, pharmaceutically produced transdermal cannabidiol therapies for orphan neurobehavioral disorders, including Fragile X Syndrome and 22q deletion syndrome. As of July 1, 2024, Zynerba Pharmaceuticals, Inc. was renamed and is known as Harmony Biosciences Management, Inc.

In April 2024, we expanded into orexin science through a sublicense agreement with Bioprojet for an orexin 2 receptor agonist (“BP1.15205”) in preclinical development for narcolepsy and other potential indications. Under the sublicense agreement the Company obtained the exclusive right to develop, manufacture and commercialize BP1.15205 in the United States and Latin American territories, which are rights originally licensed from Teijin Pharma, the innovator of BP1.15205. We further broadened our portfolio into rare epilepsy when the Company acquired Epygenix Therapeutics, Inc. (“Epygenix”) in April 2024. As a result, the Company now has an exclusive license relating to the use of clemizole hydrochloride, initially for the treatment of Dravet Syndrome (“DS”) and Lennox-Gastaut Syndrome (“LGS”), and a liquid formulation of lorcaserin for the treatment of developmental and epileptic encephalopathies.

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 retained earnings of \$138,417 and \$2,216, as of September 30, 2025, and December 31, 2024, respectively. As of September 30, 2025, the Company had cash, cash equivalents and investments of \$778,412.

The Company believes that its existing cash, cash equivalents and investments on hand as of September 30, 2025, as well as additional cash generated from operating and financing activities will meet its operational liquidity needs and fund potential investing activities for at least the next twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated balance sheet as of September 30, 2025, the unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2025, and 2024, and the unaudited condensed consolidated statements of operations and comprehensive income and the unaudited condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 2025, and 2024, are unaudited. The balance sheet as of December 31, 2024, was derived from audited financial statements as of and for the year ended December 31, 2024. 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, 2024, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2025, and the results of its operations and its cash flows for the nine months ended September 30, 2025, and 2024. 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, 2024.

Reclassifications

Certain prior period amounts within the unaudited condensed consolidated balance sheets have been reclassified to conform to current period presentation. In particular, restricted cash was previously classified as a separate caption and is now included within other noncurrent assets. The reclassification of this item 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, including generic competition; 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 commercialized 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 the Company 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 payable pursuant to commercial and government contracts, accrued research and development expenses, stock-based compensation expense and income taxes.

Operating Segments

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 Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company has determined it operates in a single operating segment, rare neurological diseases and, therefore, has one reportable segment. The Company holds all its tangible assets, conducts its operations, and generates its revenue in the United States.

Fair Value of Financial Instruments

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

It is the Company's policy to measure non-financial assets and liabilities at fair value on a non-recurring basis. These non-financial assets and liabilities are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (such as evidence of impairment), which, if material, are disclosed in the accompanying footnotes.

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

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

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

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

Money market funds are classified as Level 1 fair value instruments. Investments in available-for-sale debt securities are classified as Level 2 and carried at fair value, which we estimate utilizing a third-party pricing service. The pricing service utilizes industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. We validate valuations obtained from third-party services by obtaining market values from

other pricing sources. The Company did not classify any assets or liabilities as Level 3 as of September 30, 2025, or December 31, 2024.

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	
	September 30, 2025	December 31, 2024
Cash and cash equivalents	\$ 646,999	\$ 453,001
Restricted cash included in other noncurrent assets	270	270
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	<u>\$ 647,269</u>	<u>\$ 453,271</u>

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 six 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 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 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 for uncollectible amounts, if necessary. As of September 30, 2025, three customers accounted for 100% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 38% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 36% of gross accounts receivable; and PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 26% of gross accounts receivable. As of December 31, 2024, three customers accounted for 100% of gross accounts

receivable; CVS Caremark, which accounted for 39% of gross accounts receivable, Pantherx, which accounted for 31% of gross accounts receivable; and Accredo, which accounted for 30% of gross accounts receivable.

For the nine months ended September 30, 2025, three customers accounted for 100% of gross product revenue; CVS Caremark accounted for 38% of gross product revenue; Accredo accounted for 36% of gross product revenue; and Pantherx accounted for 26% of gross product revenue. For the nine months ended September 30, 2024, three customers accounted for 100% of gross product revenue; CVS Caremark accounted for 40% of gross product revenue; Accredo accounted for 33% of gross product revenue; and Pantherx accounted for 27% of gross product revenue.

The Company depends on a single supplier of the active pharmaceutical ingredient (“API”) for its commercial product, WAKIX, and single API suppliers for each of its potential product candidates.

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, *Acquisitions*, for a more detailed discussion of the Company’s acquisition of Epygenix.

Recently Adopted 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 was effective for annual reporting periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption was permitted. ASU 2023-07 was required to be applied retrospectively to all prior periods presented in the financial statements. The Company adopted this guidance in the fourth quarter of 2024. This pronouncement addresses disclosures only and had no impact on the Company’s consolidated financial statements.

Recently Issued Accounting Pronouncements

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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures* (Subtopic 220-40). ASU 2024-03 requires disclosure, in the notes to the financial statements, of specified information about certain costs and expenses, including amounts of purchases of inventory, employee compensation, depreciation, and intangible asset amortization included in each relevant expense caption, as well as a qualitative description of amounts remaining in relevant expense

captions that are not separately disaggregated quantitatively. ASU 2024-03 also requires disclosure of the total amount of selling expenses and, in annual periods, an entity's definition of selling expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. The guidance may be applied prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2024-03 will have on the Company's consolidated financial statements.

4. ACQUISITIONS

Acquisition of Zynerba

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.

In September 2025, the Company achieved a clinical milestone for ZYN002 that triggered a \$15.0 million payment to CVR holders, which will be paid in the fourth quarter of 2025.

Acquisition of Epygenix

In April 2024, the Company acquired Epygenix pursuant to the terms of a stock purchase agreement. The Company paid the former stockholders of Epygenix up front consideration of \$35,000 less a working capital adjustment. In addition, the Company will 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. As a result, the Company now has an exclusive license relating to the use of clemizole, initially for the treatment of DS and LGS.

The acquisition of Epygenix was accounted for as an asset acquisition under ASC Topic 805, Business Combinations. The Company did not acquire any outputs and there was not an acquired substantive process in place to create outputs. 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. In accordance with the accounting for asset acquisitions, an entity that acquires IPR&D assets in an asset acquisition follows the guidance in ASC Topic 730, Research and Development, which requires that both tangible and intangible identifiable research and development assets with no alternative future use be allocated a portion of the consideration transferred and recorded as research and development expense at the acquisition date. As a result, the Company recorded a charge of \$17,095 related to acquired in-process research and development expense during the year ended December 31, 2024.

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:

	September 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	\$ 10,268	6	—	\$ 10,274
Corporate debt securities	15,301	10	(3)	15,308
Total short-term investments	<u>\$ 25,569</u>	<u>16</u>	<u>(3)</u>	<u>\$ 25,582</u>
Long-term:				
Commercial paper	\$ 796	1	—	\$ 797
Corporate debt securities	87,378	276	(1)	87,653
U.S. government securities	17,313	68	—	17,381
Total long-term investments	<u>\$ 105,487</u>	<u>345</u>	<u>(1)</u>	<u>\$ 105,831</u>
	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term:				
Commercial paper	\$ 7,670	9	(1)	\$ 7,678
Corporate debt securities	6,495	12	—	6,507
Total short-term investments	<u>\$ 14,165</u>	<u>21</u>	<u>(1)</u>	<u>\$ 14,185</u>
Long-term:				
Corporate debt securities	86,700	192	(142)	86,750
U.S. government securities	22,128	11	(15)	22,124
Total long-term investments	<u>\$ 108,828</u>	<u>203</u>	<u>(157)</u>	<u>\$ 108,874</u>

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 in 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 September 30, 2025, and December 31, 2024, 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 September 30, 2025, or December 31, 2024.

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

	September 30, 2025			December 31, 2024		
	Total	Level 1	Level 2	Total	Level 1	Level 2
Assets						
Cash equivalents	\$ 280,740	280,740	—	\$ 303,545	303,545	—
Commercial paper	11,071	—	11,071	7,678	—	7,678
Corporate debt securities	102,961	—	102,961	93,257	—	93,257
U.S. government securities	17,381	—	17,381	22,124	—	22,124
Total	<u>\$ 412,153</u>	<u>280,740</u>	<u>131,413</u>	<u>\$ 426,604</u>	<u>303,545</u>	<u>123,059</u>

7. INVENTORY

Inventory, net consisted of the following:

	As of	
	September 30, 2025	December 31, 2024
Raw materials	\$ 1,120	\$ 944
Work in process	4,198	3,489
Finished goods	1,728	2,765
Inventory, gross	7,046	7,198
Reserve for excess inventory	(164)	—
Total inventory, net	<u>\$ 6,882</u>	<u>\$ 7,198</u>

8. INTANGIBLE ASSETS

In August 2019, the Company received FDA approval of WAKIX for the treatment of EDS in adult patients with narcolepsy. This event triggered a milestone payment of \$75,000 under the provisions of the 2017 LCA which the Company capitalized as an intangible asset. The Company determined a useful life of 10 years for the intangible asset, and, as of September 30, 2025, the remaining useful life was 4.0 years.

In October 2020, the Company received FDA approval for the New Drug Application (“NDA”) for WAKIX for the treatment of cataplexy in adult patients with narcolepsy. This event triggered a milestone payment of \$100,000 under the provisions of the 2017 LCA which the Company capitalized as an intangible asset and paid in January of 2021. The Company determined a useful life of 9 years for the intangible asset, and, as of September 30, 2025, the remaining useful life was 4.0 years.

In February 2022, the Company attained \$500,000 in life-to-date aggregate net sales of WAKIX in the United States. This event triggered a final \$40,000 payment under the provisions of the 2017 LCA which the Company capitalized as an intangible asset and paid in March of 2022. The Company determined a useful life of 7.6 years for the intangible asset, and, as of September 30, 2025, the remaining useful life was 4.0 years.

Amortization expense was \$5,961 for each of the three months ended September 30, 2025, and 2024, respectively, and \$17,883 for each of the nine months ended September 30, 2025, and 2024, respectively, and is recorded in general and administrative 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,	
2025 (excluding the nine months ended September 30, 2025)	\$ 5,962
2026	23,845
2027	23,845
2028	23,845
2029	17,883
Thereafter	—
Total	\$ 95,380

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

	As of	
	September 30, 2025	December 31, 2024
Gross Carrying Amount	\$ 215,000	\$ 215,000
Accumulated Amortization	(119,620)	(101,737)
Net Book Value	<u>\$ 95,380</u>	<u>\$ 113,263</u>

9. LICENSE AGREEMENTS AND ASSET PURCHASE AGREEMENTS

Bioprojet Agreements

In July 2017, Harmony entered into the 2017 LCA with 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 \$57,323 and \$40,295 for the three months ended September 30, 2025, and 2024, respectively, and \$122,663 and \$95,232 for the nine months ended September 30, 2025, and 2024, respectively for sales-based, trademark and tiered royalties recognized as cost of product sold. As of September 30, 2025, and December 31, 2024, the Company had accrued \$57,323 and \$51,746, respectively, for sales-based, trademark and tiered royalties.

In July 2022, Harmony entered into 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.

In April 2024, the Company announced that it entered into a sublicense agreement with Bioprojet for an orexin-2 receptor agonist (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 Medicinal Product Dossier (“IMPD”) Application currently anticipated in the second half of 2025. Under the Sublicense, the Company paid Bioprojet an upfront license fee of \$25,500, which the Company recognized as an IPR&D charge recorded in research and development within the consolidated statements of operations and comprehensive income for the year ended December 31, 2024, 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.

ConSynance Agreement

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 consolidated statement of operations and comprehensive income for the year ended December 31, 2023. In September 2024, the Company achieved a milestone for preclinical proof-of-concept, which triggered a \$1,000 payment under the provisions of the APA, which the Company recognized as an IPR&D charge recorded in research and development within the consolidated statement of operations and comprehensive income for the year ended December 31, 2024. There are additional payments due under the APA upon the achievement of certain milestones including \$19,000 for development milestones, \$44,000 for regulatory milestones and \$110,000 for sales milestones.

CiRC Agreement

In June 2025, the Company entered into a research collaboration, option and license agreement (the “CiRC Agreement”) with a related party, CiRC Biosciences, Inc. (“CiRC”). Under this agreement, the Company and CiRC will collaborate on the research and development of two discovery-stage candidates (together the “Candidates”) using cell replacement therapy for treatment of refractory epilepsies and treatment-resistant narcolepsy. In connection with the CiRC Agreement, the Company paid CiRC an upfront fee of \$15,000, which was recognized as an IPR&D charge recorded in research and development within the unaudited condensed consolidated statements of operations and comprehensive income for the nine months ended September 30, 2025. The Company will also be obligated to pay \$2,000 to CiRC upon the achievement of certain research milestones for each of the Candidates. In addition, the Company has an option to obtain an exclusive license for each of the Candidates that would grant the Company global rights to develop, manufacture and commercialize each Candidate. Upon exercise of each option, the Company would be obligated to pay an option exercise fee of \$8,000, or \$16,000 in the aggregate if the options related to both Candidates were to be exercised, and the Company would be obligated upon achievement to pay future development, regulatory and sales-based milestones, as well as royalties on sales of any product derived from the Candidates. Refer to Note 19, *Related-Party Transactions*, for further discussion of related party considerations for the CiRC Agreement.

10. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of	
	September 30, 2025	December 31, 2024
Royalties due to Bioprojet	\$ 57,323	\$ 51,746
Rebates and other sales deductions	65,092	50,542
Interest	2,279	2,834
Sales and marketing	5,578	2,166
Research and development	9,135	9,014
Milestone payments	15,000	—
Professional fees, consulting, and other services	5,055	3,047
Other expenses	1,840	1,291
	<u>\$ 161,302</u>	<u>\$ 120,640</u>

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, which was subsequently amended in September 2023. The TLA Credit Agreement, as amended, provides for a five-year senior secured term loan (the “TLA Term Loan”) in an aggregate principal amount of \$200,000.

The repayment schedule for the TLA Term Loan consists of quarterly \$3,750 principal payments, which commenced 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 TLA Term Loan bears 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 TLA Term Loan as a result of the transactions, less debt issuance costs of \$2,997, was \$197,003. The debt issuance costs related to the TLA Term Loan will be amortized as additional interest expense over the loan term of the TLA Credit Agreement. The fair value of the TLA Term Loan as of September 30, 2025, was \$168,253.

Long-term debt, net consisted of the following:

	September 30, 2025	December 31, 2024
Principal amount	\$ 170,000	\$ 181,250
Unamortized debt discount associated with debt financing costs	(1,494)	(1,984)
Total debt, net	168,506	179,266
Less current portion	(20,000)	(16,250)
Long-term debt, net	<u>\$ 148,506</u>	<u>\$ 163,016</u>

Future minimum payments relating to long-term debt, net as of September 30, 2025, for the periods indicated below consisted of the following:

Years ending December 31,

2025 (excluding the nine months ended September 30, 2025)	\$ 5,000
2026	20,000
2027	20,000
2028	125,000
2029	—
Thereafter	—
Total	\$ 170,000

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 consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Interest on principal balance	\$ 3,460	\$ 4,173	\$ 10,613	\$ 12,756
Amortization of deferred financing costs	160	175	490	531
Total term loan interest expense	\$ 3,620	\$ 4,348	\$ 11,103	\$ 13,287

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 was set to expire 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 were extended through October 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 primarily used by its sales force 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 \$394 and \$491 for the three months ended September 30, 2025, and 2024, respectively, and \$1,459 and \$1,622 for the nine months ended September 30, 2025, and 2024, respectively.

As of September 30, 2025, the weighted-average remaining lease term for operating leases was 1.7 years and the weighted-average discount rate for operating leases was 7.72%.

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

Leases	Classification	September 30, 2025	December 31, 2024
Assets			
Operating lease right-of-use assets	Other noncurrent assets	\$ 1,228	\$ 2,122
Liabilities			
Operating lease liability, current portion	Other current liabilities	\$ 825	\$ 1,318
Operating lease liability, long-term	Other long-term liabilities	403	822
Total operating lease liabilities		<u>\$ 1,228</u>	<u>\$ 2,140</u>

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

	September 30, 2025	September 30, 2024
Operating cash flows from operating leases	\$ 1,478	\$ 1,623
Right of use assets obtained in exchange for operating lease obligations	\$ 273	\$ 1,612

Future payments under non-cancelable operating leases with initial terms of one year or more as of September 30, 2025, consisted of the following:

Years ending December 31,	
2025 (excluding the nine months ended September 30, 2025)	\$ 246
2026	746
2027	261
2028	52
2029	—
Thereafter	—
Total lease payments	<u>1,305</u>
Less: imputed interest	(77)
Total lease liabilities	<u>\$ 1,228</u>

13. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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. Accruals may be adjusted from time to time, as appropriate, in light of new information. The amount of loss incurred in relation to matters for which an accrual has been established may be higher or lower than the amounts accrued. Any expenses, fines, fees, penalties, judgments or settlements that might be incurred by the Company in connection with proceedings could have a material adverse effect on the Company's results of operations and financial condition. As of September 30, 2025, there were no material claims or lawsuits outstanding other than the Abbreviated New Drug Application ("ANDA") litigation discussed below.

ANDA Litigation

In September 2023, the Company and its 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, the Company 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. In June 2025, the Company reached an agreement with Lupin to resolve the dispute over Lupin’s ANDA to market a generic version of WAKIX. Under the terms of the settlement agreement, the litigation between the parties in the United States District Court for the District of Delaware will be dismissed, and Lupin will have a license to sell its generic product beginning January 2030, or earlier under certain circumstances.

In October 2023, the Company 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, the Company 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, the Company 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, the Company 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, the Company, 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 March 2025, the Company reached an agreement with Annora to resolve the dispute over Annora’s ANDA for a generic pitolisant hydrochloride product. Under the terms of the settlement agreement, the litigation between the parties in the United States District Court for the District of Delaware was ended on March 31, 2025, and Annora will have a license to sell its generic product beginning January 2030, or earlier under certain circumstances.

In October 2023, MSN Pharmaceuticals Inc. (“MSN Pharma”) sent correspondence to the Company 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.

In April 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.

In August 2024, the Company and Bioprojet received further notice from AET pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the "Second AET Notice Letter") that AET has submitted 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. The Second AET Notice Letter asserts that its 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 August 13, 2024, we, Bioprojet and Bioprojet Pharma filed a complaint in the United States District Court for the District of Delaware for patent infringement of the '947 patent and the '197 patent against AET.

In October 2024, the Company reached an agreement with Novugen Pharma to resolve the dispute over Novugen's ANDA for a generic pitolisant hydrochloride product. Under the terms of the settlement agreement, the litigation between the parties in the United States District Court for the District of Delaware was ended on November 4, 2024, and Novugen will have a license to sell its generic product beginning January 2030, or earlier under certain circumstances.

In December 2024, the Company and Bioprojet received further notice from Lupin pursuant to 21 U.S.C. § 355(j) *et seq.* and 21 C.F.R. § 314.95 *et seq.* (the "Second Lupin Notice Letter") that Lupin has submitted the Lupin 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. The Second Lupin Notice Letter asserts that its 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 January 24, 2025, we, Bioprojet and Bioprojet Pharma filed a complaint in the United States District Court for the District of Delaware for patent infringement of the '947 patent and the '197 patent against Lupin. As noted above, in June 2025, the Company reached an agreement with Lupin to resolve the dispute over Lupin's ANDA to market a generic version of WAKIX. Under the terms of the settlement agreement, the litigation between the parties in the United States District Court for the District of Delaware will be dismissed, and Lupin will have a license to sell its generic product beginning January 2030, or earlier under certain circumstances.

The resolution of one or more of the ANDA litigation matters against the Company could have a significant negative effect on the Company's results of operations.

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 and nine months ended September 30, 2025, and 2024, no shares of common stock were repurchased by the Company under the October 2023 Repurchase Program. As of September 30, 2025, 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"), Stock Appreciation Rights ("SARs"), restricted stock, dividend equivalents, restricted stock units ("RSUs") and other stock or cash-based awards.

Stock options and SARs under the 2020 Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). RSUs vest over the vesting period specified in the applicable award agreement, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). As of September 30, 2025, there were 8,603,721 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, SARs or restricted stock. Following the adoption of the 2020 Plan, no further grants have been, or will be, made under the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of outstanding awards granted under it.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2025:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (\$000's)
Awards outstanding—December 31, 2024	7,157,235	\$ 32.48	6.7	
Awards issued	1,399,081	\$ 36.24		
Awards exercised	(323,878)	\$ 22.98		
Awards forfeited	(248,080)	\$ 37.11		
Awards outstanding—September 30, 2025	<u>7,984,358</u>	<u>\$ 33.38</u>	<u>6.5</u>	<u>\$ 16,947</u>
Awards exercisable—September 30, 2025	<u>5,532,221</u>	<u>\$ 32.34</u>	<u>5.6</u>	<u>\$ 16,766</u>
Awards unvested—September 30, 2025	<u>2,452,137</u>	<u>\$ 35.72</u>	<u>8.7</u>	<u>\$ 181</u>

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2025, was \$36.24. The total intrinsic value of stock options exercised for the nine months ended September 30, 2025, was \$4,214.

Stock Appreciation Rights

The following table summarizes SARs activity for the nine months ended September 30, 2025:

	Number of Awards	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (\$000's)
Awards outstanding—December 31, 2024	43,208	\$ 9.38	4.3	
Awards issued	—	\$ —		
Awards exercised	(9,737)	\$ —		
Awards forfeited	—	\$ —		
Awards outstanding—September 30, 2025	<u>33,471</u>	<u>\$ 8.72</u>	<u>3.4</u>	<u>\$ 372,225</u>
Awards exercisable—September 30, 2025	<u>33,471</u>	<u>\$ 8.72</u>	<u>3.4</u>	<u>\$ 372,225</u>

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2025:

	Number of Awards	Weighted-Average Grant Date Fair Value
Awards outstanding—December 31, 2024	638,900	\$ 30.90
Awards issued	458,650	\$ 37.61
Awards vested	(215,795)	\$ 30.99
Awards forfeited	(82,168)	\$ 33.28
Awards outstanding—September 30, 2025	<u>799,587</u>	<u>\$ 34.48</u>

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 2020 Plan during the nine months ended September 30, 2025, and 2024 was \$37.61 and \$30.62, respectively.

Value of Stock Options and SARs

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

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

	As of	
	September 30, 2025	December 31, 2024
Dividend yield	0.00 %	0.00 %
Expected volatility	69.18 - 71.43 %	69.84 - 72.98 %
Risk-free interest rate	3.74 - 4.44 %	3.51 - 4.65 %
Lack of marketability discount	0.00 %	0.00 %
Expected term (years)	1.5 - 6.1	1.8 - 6.1

Stock-Based Compensation Expense

Stock-based compensation expense for the three and nine months ended September 30, 2025, and 2024, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income in the following line items:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development expense	\$ 2,258	\$ 1,910	\$ 6,673	\$ 4,964
Sales and marketing expense	1,494	1,815	5,890	5,909
General and administrative expense	7,072	7,723	22,105	21,972
	<u>\$ 10,824</u>	<u>\$ 11,448</u>	<u>\$ 34,668</u>	<u>\$ 32,845</u>

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 September 30, 2025, the total unrecognized stock-based compensation expense was \$51,371 and \$22,743 for stock options and RSUs,

respectively. These amounts will be recognized in the Company's consolidated statement of operations over a weighted average period of 2.5 years and 2.9 years for stock options and RSUs, respectively.

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 0 and 1,206 shares issued under the ESPP for the three months ended September 30, 2025, and 2024, respectively. There were 11,772 and 11,913 shares issued under the ESPP for the nine months ended September 30, 2025, and 2024, respectively. The discount on the ESPP was \$76 and \$72 for the three months ended September 30, 2025, and 2024, respectively, and \$201 and \$230 for the nine months ended September 30, 2025, and 2024, respectively, and is recorded within stock-based compensation expense.

16. SEGMENT INFORMATION

The Company has one reportable segment: rare neurological diseases. The rare neurological diseases segment consists of the Company's commercial product, WAKIX, and its potential product candidates, that focus on patients living with rare neurological diseases who have unmet needs. The Company currently derives all of its revenue from sales of WAKIX, which is used in the treatment of EDS and cataplexy in adult patients with narcolepsy and the treatment of EDS in pediatric patients six years and older with narcolepsy and manages its business activities on a consolidated basis.

The accounting policies of the rare neurological diseases segment are consistent with those described in Note 3, *Summary of Significant Accounting Policies*, and the measure of segment assets is reported on the consolidated balance sheets as total assets. The Company's CODM is the chief executive officer. The CODM assesses performance of the rare neurological diseases segment using net income as reported in the consolidated statements of operations and comprehensive income. Net income is assessed by the CODM to make decisions on how to allocate resources, such as reinvesting profits into the rare neurological diseases segment or pursuing potential investing activities.

The following table summarizes segment revenue and significant segment expenses for the three and nine months ended September 30, 2025, and 2024:

Rare Neurological Diseases Segment				
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net product revenue	\$ 239,455	\$ 186,038	\$ 624,677	\$ 513,467
Less:				
Cost of product sold (a)	59,643	42,777	129,777	102,394
Research and development (b)	37,704	22,477	102,988	62,600
Sales and marketing (c)	28,055	25,761	84,443	77,407
General and administrative (d)	16,774	14,897	54,986	41,383
Depreciation and amortization	5,968	5,968	17,903	18,144
Stock-based compensation	10,824	11,448	34,668	32,845
Interest expense	3,621	4,348	11,103	13,287
Interest income	(5,730)	(4,932)	(16,070)	(14,065)
Income tax expense	16,625	16,077	38,103	39,631
Other segment items (e)	15,106	1,124	30,575	43,823
Consolidated net income	\$ 50,865	\$ 46,093	\$ 136,201	\$ 96,018

(a) Cost of product sold excluding depreciation.

(b) Research and development excluding stock-based compensation and IPR&D.

(c) Sales and marketing excluding stock-based compensation.

(d) General and administrative excluding stock-based compensation, depreciation and amortization.

(e) Other segment items include other expense, net and IPR&D charges.

17. 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator				
Net income	\$ 50,865	\$ 46,093	\$ 136,201	\$ 96,018
Denominator				
Net income per share of common stock - basic	\$ 0.88	\$ 0.81	\$ 2.36	\$ 1.69
Net income per share of common stock - diluted	\$ 0.87	\$ 0.79	\$ 2.32	\$ 1.66
Weighted average number of shares of common stock - basic	57,550,902	56,870,234	57,655,272	56,815,167
Weighted average number of shares of common stock - diluted	58,717,910	58,103,963	58,738,361	57,754,016

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Stock options, SARs, and RSUs to purchase common stock	1,167,008	1,233,729	1,083,089	938,849

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Stock options, SARs, and RSUs to purchase common stock	7,650,408	6,868,642	7,734,327	7,163,522

18. INCOME TAXES

On July 4, 2025, the "One Big Beautiful Bill Act" (the "OBBBA") was enacted into law. The OBBBA contains several changes to corporate taxation, including the allowance of immediate expensing of domestic research and development expenses. As a result, the Company recorded a \$48,000 reduction to deferred tax assets related to domestic research and development expenses which is reflected in its condensed consolidated balance sheet as of September 30, 2025. The reduction in deferred tax assets will reduce the amount of federal tax payments owed by the Company for the 2025 tax year. There was no material impact to the Company's expected tax rate as a result of this legislation.

A reconciliation between the statutory federal income tax rate and the Company's effective income tax rate for the three and nine months ended September 30, 2025, and 2024 is as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Federal income tax rate	21.0 %	21.0 %	21.0 %	21.0 %
Stock-based compensation	—	(0.1)	—	(0.2)
State taxes	1.7	5.1	1.6	6.3
Credits	(2.2)	(0.9)	(2.6)	(1.2)
Nondeductible IPR&D	3.5	—	1.4	2.5
Valuation allowance	—	0.4	—	0.4
Other	0.6	0.4	0.5	0.4
Total	<u>24.6 %</u>	<u>25.9 %</u>	<u>21.9 %</u>	<u>29.2 %</u>

19. RELATED-PARTY TRANSACTIONS

The Company is a party to a right of use agreement with Paragon Biosciences, LLC ("Paragon") whereby it has access to and the right to use certain office space leased by Paragon in Chicago, IL. In addition, the Company received consulting services from Paragon during the nine months ended September 30, 2025. 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 incurred \$73 for each of the three months ended September 30, 2025, and 2024, and incurred \$401 and \$218 for the nine months ended September 30, 2025, and 2024, respectively, in expenses to Paragon, which are included in

general and administrative in the unaudited condensed consolidated statements of operations and comprehensive loss. As of September 30, 2025, and December 31, 2024, there were no amounts due to or due from Paragon included in the unaudited condensed consolidated balance sheets.

In June 2025, the Company entered into the CiRC Agreement with CiRC, an entity controlled by Paragon. The Company paid a \$15,000 upfront payment to CiRC pursuant to the CiRC Agreement which was recorded as an IPR&D charge in research and development in the unaudited condensed consolidated statements of operations and comprehensive income. As of September 30, 2025, there were no amounts due to or due from CiRC under the CiRC agreement. Refer to Note 9, *License Agreements*, for further discussion regarding the CiRC Agreement.

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, progress developing the new Pitolisant Gastro-resistant ("Pitolisant GR") and Pitolisant High Dose ("Pitolisant HD") formulations, and the development of ZYN002, BP1-15205, clemizole hydrochloride ("EPX-100") and other compounds;
- our ongoing and planned clinical trials;
- 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 Société Civile de Recherche (“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 cultivating a differentiated neuroscience company, rooted in innovation and driven by a commitment to addressing the unmet needs of patients living with neurological diseases. To date, we have focused on rare neurological diseases with a growing portfolio now spanning sleep/wake, neurobehavioral, and rare epilepsy, and we are harnessing scientific insights and pioneering approaches to advance meaningful treatments that help patients thrive. Our operations are conducted by our wholly owned subsidiaries, Harmony Biosciences, LLC and Harmony Biosciences Management, Inc.

Sleep/Wake Franchise

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 designation for the treatment of EDS and cataplexy in patients with narcolepsy in April 2018. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of 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.

We believe that pitolisant’s ability to regulate histamine mediated through histamine-3 receptor antagonist and inverse agonist activity gives it the potential to provide therapeutic benefit in other rare neurological diseases.

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 type 1, otherwise known as dystrophia myotonica (“DM1”). 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 behavioral 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 study design for the Phase 3 TEMPO study in patients with PWS, which has the potential to serve as the registrational trial and also support our efforts to seek 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 the first quarter of 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 two most prominent non-muscular symptoms in patients with DM1. The safety and tolerability profile of pitolisant in adult patients with DM1 was consistent with the established safety and tolerability profile of pitolisant with no new safety signals detected and no serious adverse events reported.

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 with or without cataplexy in children six 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. In June 2024, we announced that the FDA approved our sNDA for WAKIX for the treatment of EDS in pediatric patients six years of age and older with narcolepsy. In addition, in June 2024, the FDA did not approve our sNDA seeking to expand the WAKIX label for the treatment of pediatric patients with cataplexy. In October 2024, we held a Type A meeting with the FDA to discuss the pediatric cataplexy indication and reached alignment on a path to sNDA resubmission, which was submitted in the third quarter of 2025.

We remain committed to obtaining pediatric exclusivity for WAKIX. We believe the initiation of the PWS Phase 3 registrational trial, the TEMPO study, and our current data in pediatric narcolepsy, which resulted in the FDA's approval of WAKIX in its current pediatric indication, are supportive of our efforts in obtaining pediatric exclusivity for WAKIX.

We have expanded 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 target 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: Pitolisant GR and Pitolisant HD. Both formulations entered clinical studies in the fourth quarter of 2023. We received data from the Pitolisant GR pilot bioequivalence study, which supports further development of Pitolisant GR. In addition, we completed the Dosing Optimization study that supports imitating pitolisant GR at the therapeutic dose of 17.8mg without titration. We initiated the pivotal bioequivalence study in the first quarter of 2025 and anticipate the topline data readout in the fourth quarter of 2025. We anticipate a PDUFA date for Pitolisant GR in the first quarter of 2027. We received data from the Pitolisant HD pilot pharmacokinetics study in June 2024, which also supports advancing this development program toward pivotal trials. In addition, we submitted an Investigational New Drug ("IND") application for pitolisant HD with the FDA and preparations are ongoing to initiate Phase 3 registrational trials in narcolepsy and idiopathic hypersomnia ("IH") in the fourth quarter of 2025. We anticipate a PDUFA date for the Pitolisant HD narcolepsy and IH programs in 2028. A phase 1b study was conducted to evaluate the safety and tolerability of pitolisant at repeat doses of up to 180mg and the initial results are consistent with the known safety profile of pitolisant and support advancement of the Pitolisant HD development program. Utility patents have been filed for Pitolisant GR and Pitolisant HD, with the potential for patent protection to the mid-2040's.

In April 2024, we entered into a sublicense agreement with Bioprojet for an orexin-2 receptor agonist (OX2R) ("BP1.15205") to be evaluated for the treatment of narcolepsy and other potential indications (the "Sublicense"). Under the Sublicense, we obtained the exclusive right to develop, manufacture and commercialize BP1.15205 in the United States and Latin American territories, which are rights that Bioprojet originally licensed from Teijin Pharma, the innovator of BP1.15205. In June 2025, we announced positive pre-clinical data demonstrating significant wake-promoting and cataplexy-suppressing effects in a standard transgenic mouse model of narcolepsy type 1, and presented safety data from the three month GLP toxicity studies in two different species. We filed an investigational medicinal product dossier ("IMPD") with the EMA and are on track to begin first-in-human studies in the fourth quarter of 2025 with topline data anticipated in 2026.

In June 2025, we entered into a research collaboration, option and license agreement (the "CiRC Agreement") with a related party, CiRC Biosciences, Inc. ("CiRC"). Under this agreement, Harmony and CiRC will collaborate on the research and development of two discovery-stage candidates (together the "Candidates") using cell replacement therapy for the treatment of refractory epilepsies and treatment-resistant narcolepsy.

In August 2021, we acquired HBS-102, a Melanin-concentrating hormone receptor type 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 conducted a preclinical PoC study to assess the effect of HBS-102 on hyperphagia, weight gain and other metabolic parameters in a mouse model of PWS. The final report was received during the third quarter of 2024. In addition, a 13-week toxicology study has been completed. The results from these preclinical studies are encouraging.

Neurobehavioral Franchise

In October 2023, we acquired Zynerba Pharmaceuticals, Inc. (“Zynerba”), adding global rights to develop, manufacture and commercialize ZYN002, which is a pharmaceutically manufactured 100% synthetic, patent protected permeation enhanced cannabidiol gel for transdermal delivery. Transdermal delivery provides better gastrointestinal tolerability and minimize the potential for drug interactions or impacts on liver function tests by avoiding first-pass metabolism in the liver. The most common adverse effect observed in clinical studies has been application site pain, which has occurred in less than 7% of patients. In September 2025, ZYN002 completed a Phase 3 registrational trial, the RECONNECT study, for the treatment of Fragile X Syndrome (“FXS”), which was designed to confirm the positive findings from the prespecified analysis of the primary outcome in the subgroup of patients with complete methylation from the Phase 2/3 CONNECT study conducted by Zynerba. The RECONNECT study did not meet the primary endpoint of improvement in social avoidance primarily due to a higher than expected placebo response rate. We are currently reviewing the full data set from the RECONNECT study and determining the next steps for the FXS program. We have paused the initiation of a Phase 3 study in 22q deletion syndrome, another rare disorder with prominent neurobehavioral symptoms.

Rare Epilepsy Franchise

In April 2024, we acquired Epygenix Therapeutics, Inc. (“Epygenix”), pursuant to the terms of a stock purchase agreement (the “Epygenix Agreement”). As a result, we now have an exclusive license relating to the use of EPX-100 for the treatment of Dravet Syndrome (“DS”), Lennox-Gastaut Syndrome (“LGS”) and other developmental and epileptic encephalopathies (“DEEs”). Patients with both conditions often encounter severe refractory epilepsy and extreme co-morbidities or mortality without effective treatments, even with polypharmacy. As such, there is a recognized need for improved treatment options for both conditions. We believe the total addressable market for EPX-100 among patients with DS is approximately 5,000 people based on an estimated current DS prevalence of approximately 8,600 cases and approximately 7,000 diagnosed DS cases. We believe the total addressable market for EPX-100 among patients with LGS is approximately 35,000 people based on an estimated current LGS prevalence of approximately 48,000 cases and 44,000 diagnosed LGS cases. EPX-100 has been granted orphan drug designation and rare pediatric disease designation by the FDA for treatment of both DS and LGS. EPX-100 is currently in two Phase 3 registrational clinical trials, one for each of DS (the ARGUS Study) and LGS (the LIGHTHOUSE Study).

Additionally, we are currently developing a liquid formulation of lorcaserin for the treatment of DEEs (“EPX-200”), another asset acquired pursuant to the terms of the Epygenix Agreement. EPX-200 is currently in the pre-IND phase.

Commercial Performance Metrics

We have continued to see growth in the number of unique healthcare professional (“HCP”) prescribers of WAKIX since it became available in November 2019. As of September 30, 2025, there are approximately 9,000 HCPs who treat patients living with narcolepsy, with approximately 4,000 enrolled in oxybate risk-evaluation and mitigation strategies (“REMS”) and approximately 5,000 HCPs who do not participate in the oxybate REMS programs. The average number of patients on WAKIX for the three months ended September

30, 2025, was approximately 8,100. Additionally, as of September 30, 2025, we have formulary access for more than 80% of all insured lives (Commercial, Medicare and Medicaid) in the United States.

Financial Operations Overview

Net Product Revenue

Net product revenue includes revenue from 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 patient 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, depreciation 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 four years from the date of manufacture, with the earliest expiration of current inventory expected to be January 2027. 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 2027, with additional API on-hand inventory to support at least two years 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 PWS and DM1 and the development of our product candidates ZYN002, EPX-100, EPX-200 Pitolisant GR, Pitolisant HD, BP1.15205 and HBS-102. 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 add 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 clinical research organizations (“CROs”), and contract development and manufacturing organizations (“CDMOs”);
- manufacturing costs in connection with producing materials for use in conducting clinical trials;
- costs related to packaging, labelling and distribution 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 CDMOs, 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 as we advance our current clinical development programs and prepare to seek regulatory approval for additional indications for pitolisant, complete the Phase 3 clinical trials for EPX-100 and advance the development of Pitolisant GR, Pitolisant HD, BP1.15205, EPX-200 and HBS-102 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 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, the treatment of EDS in pediatric patients 6 years of age and older 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, legal fees, including ANDA litigation expenses, and professional fees, including tax and accounting, insurance 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. Additionally, we received consulting services from Paragon. We paid fees of \$0.1 million and \$0.4 million to Paragon related to rent and consulting services for the three and nine months ended September 30, 2025, respectively.

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:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
	<u>(In thousands)</u>		<u>(In thousands)</u>	
Net product revenue	\$ 239,455	\$ 186,038	\$ 624,677	\$ 513,467
Cost of product sales	59,650	42,778	129,797	102,406
Gross profit	179,805	143,260	494,880	411,061
Operating expenses:				
Research and development	54,962	25,387	139,661	111,159
Sales and marketing	29,549	27,576	90,333	83,316
General and administrative	29,807	28,587	94,974	81,487
Total operating expenses	114,318	81,550	324,968	275,962
Operating income	65,487	61,710	169,912	135,099
Other (expense) income, net	(106)	(124)	(575)	(228)
Interest expense	(3,621)	(4,348)	(11,103)	(13,287)
Interest income	5,730	4,932	16,070	14,065
Net income before provision for income taxes	67,490	62,170	174,304	135,649
Income tax expense	(16,625)	(16,077)	(38,103)	(39,631)
Net income	<u>\$ 50,865</u>	<u>\$ 46,093</u>	<u>\$ 136,201</u>	<u>\$ 96,018</u>

Net Product Revenue

Net product revenue increased by \$53.4 million, or 28.7%, for the three months ended September 30, 2025, and increased by \$111.2 million, or 21.7%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The increase for the three months ended September 30, 2025, was primarily due to a 26.8% increase in the number of units shipped, and the impact of a 7.0% price increase partially offset by higher rebates of approximately 5.1%. The increase for the nine months ended September 30, 2025, was primarily due to an 18.0% increase in the number of units shipped, and the impact of a 7.0% price increase partially offset by higher rebates of approximately 3.0%. The price increase occurred in January 2025.

Cost of Product Sales

Cost of product sales increased by \$16.9 million, or 39.4%, for the three months ended September 30, 2025, and increased by \$27.4 million, or 26.7%, for the nine months ended September 30, 2025, compared to the same period in 2024. Cost of product sales as a percentage of net product revenue was 24.9% and 20.8% for the three and nine months ended September 30, 2025, respectively, compared to 23.0% and 19.9% for the three and nine months ended September 30, 2024, respectively. The increase in cost of product sales in both comparable periods was primarily due to higher royalties as a result of the increase in net product revenue of WAKIX. The increase in cost of product sales as a percentage of net revenue in both comparable periods was due to triggering a higher royalty tier under the 2017 LCA earlier in 2025 compared to 2024.

Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
	(in thousands)			(in thousands)		
Pitolisant	\$ 6,651	\$ 7,483	\$ (832)	\$ 18,385	\$ 23,868	\$ (5,483)
ZYN002	6,994	4,172	2,822	21,025	11,777	9,248
EPX-100	7,699	2,069	5,630	22,144	2,069	20,075
IPR&D	15,000	1,000	14,000	30,000	43,595	(13,595)
Pitolisant GR and Pitolisant HD	4,029	865	3,164	8,067	2,358	5,709
Personnel expenses	8,100	6,206	1,894	24,133	17,402	6,731
Stock-based compensation	2,243	1,910	333	6,658	4,964	1,694
Other research and development	4,246	1,682	2,564	9,249	5,126	4,123
Total	\$ 54,962	\$ 25,387	\$ 29,575	\$ 139,661	\$ 111,159	\$ 28,502

Research and development expenses increased by \$29.6 million, or 116.5%, for the three months ended September 30, 2025, and increased by \$28.5 million, or 25.6%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The increase for the three months ended September 30, 2025 was primarily driven by IPR&D charges of \$15.0 million related to a clinical milestone achieved for ZYN002 that occurred during the three months ended September 30, 2025, a combined \$11.6 million increase in research and development expenses for EPX-100, ZYN002 and Pitolisant GR and HD as we progressed clinical trials and manufacturing, a \$1.9 million increase in personnel costs associated with higher headcount, a \$0.3 million increase in stock compensation associated with new equity awards and \$2.6 million in other research and development expenses primarily associated with BP.15205, offset by a \$0.8 million decrease in clinical development associated with pitolisant, driven by a decrease in clinical trial expenses for the IH indication, and a \$1.0 million preclinical milestone achieved for HBS-102 that occurred during the three months ended September 30, 2024.

The increase for the nine months ended September 30, 2025 was primarily driven by IPR&D charges of \$30.0 million related to a \$15.0 million clinical milestone achieved for ZYN002 and a \$15.0 million upfront fee related to the CiRC Agreement, a combined \$35.0 million increase in research and development expenses for EPX-100, ZYN002 and Pitolisant GR and HD as we progressed clinical trials and manufacturing, a \$6.7 million increase in personnel costs associated with higher headcount, a \$1.7 million increase in stock compensation associated with new equity awards and \$4.1 million in other research and development expenses primarily associated with BP.15205 offset by \$43.6 million in IPR&D charges associated with the acquisition of

Epygenix (\$17.1 million), a preclinical milestone achieved for HBS-102 (\$1.0 million) and the Bioprojet Sublicense Agreement (\$25.5 million) that occurred during the nine months ended September 30, 2024, and a \$5.5 million decrease in clinical development associated with pitolisant, driven by a decrease in clinical trial expenses for the IH indication.

Sales and Marketing Expenses

Sales and marketing expenses increased by \$2.0 million, or 7.2%, for the three months ended September 30, 2025, and increased by \$7.0 million, or 8.4%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The increase for the three months ended September 30, 2025, was primarily due to a \$1.6 million increase in patient engagement and marketing activities and a \$0.7 million increase in personnel costs, offset by a \$0.3 million decrease in stock compensation expense. The increase for the nine months ended September 30, 2025, was primarily due to a \$4.5 million increase in patient engagement and marketing activities and a \$2.5 million increase in personnel costs. The increase in patient engagement and marketing activities for both comparable periods was driven by our continued growth of WAKIX and the increase in personnel costs was driven primarily by higher headcount.

General and Administrative Expenses

General and administrative expenses increased by \$1.2 million, or 4.3%, for the three months ended September 30, 2025, and increased by \$13.5 million, or 16.6%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The increase in the three months ended September 30, 2025, was primarily due to a \$1.2 million increase in legal and professional fees, primarily associated with patent lawsuits and a \$0.6 million increase in personnel costs associated with higher headcount offset by a \$0.7 million decrease in stock compensation. The increase in the nine months ended September 30, 2025, was primarily due to a \$11.8 million increase in legal and professional fees, primarily associated with patent lawsuits, and a \$1.4 million increase in personnel costs associated with higher headcount.

Interest Expense

Interest expense decreased by \$0.7 million, or 16.7%, for the three months ended September 30, 2025, and decreased by \$2.2 million, or 16.4%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The decrease for the three and nine months ended September 30, 2025, was primarily due to lower average outstanding debt balances compared to the prior year.

Interest Income

Interest income increased by \$0.8 million, or 16.2%, for the three months ended September 30, 2025, and increased by \$2.0 million, or 14.3%, for the nine months ended September 30, 2025, compared to the same periods in 2024. The increase for the three and nine months ended September 30, 2025, was primarily a result of having higher invested balances compared to the prior year.

Income Taxes

Income tax expense was \$16.6 million, representing a 24.6% effective tax rate, for the three months ended September 30, 2025, compared to \$16.1 million, representing a 25.9% effective tax rate, for the three months ended September 30, 2024. Income tax expense was \$38.1 million, representing a 21.9% effective tax rate, for the nine months ended September 30, 2025, compared to \$39.6 million, representing a 29.2% effective tax rate, for the nine months ended September 30, 2024. The decrease in our effective tax rate for both comparable periods was primarily driven by an increase in the benefits from research and development and orphan drug credits and a decrease in state taxes, partially offset by an IPR&D charge of \$15.0 million related to ZYN002 clinical milestones that was incurred during the three months ended September 30, 2025, which is nondeductible for tax purposes. The effective tax rate of 24.6% for the three months ended September 30, 2025, included 3.5% in nondeductible IPR&D and 1.7% in state income taxes, offset by a 2.2% benefit from

credits. The effective tax rate of 21.9% for the nine months ended September 30, 2025, included 1.6% in state income taxes and 1.4% in nondeductible IPR&D, offset by a 2.6% benefit from credits.

Liquidity, Sources of Funding and Capital Resources

Overview

As of September 30, 2025, we had cash, cash equivalents, and investments of \$778.4 million, outstanding debt of \$170.0 million and retained earnings of \$138.4 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 September 30, 2025, will enable us to meet our operational liquidity needs and fund our potential investing activities for at least 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, which was subsequently amended in September 2023. The TLA Credit Agreement, as amended, provides for a five-year senior secured term loan (the “TLA Term Loan”) in an aggregate principal amount of \$200.0 million.

The repayment schedule for the TLA Term Loan consists of \$3.8 million quarterly principal payments, which commenced 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 TLA Term Loan bears 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 September 30, 2025.

Share Repurchases

In October 2023, our 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 and nine months ended September 30, 2025, no shares of common stock were repurchased by the Company under the October 2023 Repurchase Program. As of September 30, 2025, the remaining amount of common stock authorized for repurchases was \$150.0 million.

Epygenix Acquisition

In April 2024, we acquired Epygenix, pursuant to the terms of a stock purchase agreement. In connection with the closing of the transaction, we paid the former stockholders of Epygenix up front consideration of \$35.0 million less a working capital adjustment. In addition, we will also be obligated to pay up to \$130.0 million upon the achievement of development and regulatory milestones and up to \$515.0

million upon the achievement of certain sales-based milestones, in each case to Epygenix's former stockholders. As a result, the Company now has an exclusive license relating to the use of clemizole, initially for the treatment of DS and LGS.

ConSynance 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. In March 2023, we achieved a preclinical milestone, which triggered a \$0.8 million payment under the provisions of the APA, which we recognized as an IPR&D charge recorded in research and development within the consolidated statement of operations and comprehensive income for the year ended December 31, 2023. In September 2024, we achieved a milestone for preclinical proof-of concept, which triggered a \$1.0 million payment under the provisions of the APA, which we recognized as an IPR&D charge recorded in research and development within the consolidated statement of operations and comprehensive income for the year ended December 31, 2024. There are additional payments due upon the achievement of certain milestones, including \$19.0 million for development milestones, \$44.0 million for regulatory milestones and \$110.0 million for sales milestones.

Bioprojet 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 a Clinical Trial Application submission currently anticipated in the second half of 2025. Under the Sublicense, the Company paid 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.

CiRC Agreement

In June 2025, we entered into a research collaboration, option and license agreement (the "CiRC Agreement") with a related party, CiRC Biosciences, Inc. ("CiRC"). Under this agreement, we will collaborate on the research and development of two discovery-stage candidates (together the "Candidates") using cell replacement therapy for the treatment of refractory epilepsies and treatment-resistant narcolepsy. As part of the CiRC Agreement, we paid CiRC an upfront fee of \$15.0 million and we will also be obligated to pay \$2.0 million upon the achievement of certain research milestones for each of the Candidates. In addition, we have an option to obtain an exclusive license for each of the Candidates that would grant us global rights to develop, manufacture and commercialize that Candidate. We would be obligated to pay an option exercise fee of \$8.0

million, or \$16.0 million in the aggregate if the options related to both Candidates were exercised, and we would be obligated upon achievement to pay future development, regulatory and sales-based milestones, as well as royalties on sales of any product derived from the Candidates.

Recent Milestones

In September 2025, we achieved a clinical milestone for ZYN002 that triggered a \$15.0 million payment to contingent value rights holders per the terms of our acquisition of Zynerba, which will be paid in the fourth quarter of 2025.

In September 2024, we achieved a preclinical milestone that triggered a \$1.0 million payment under the provisions of the APA, which was paid in October 2024.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2025, and 2024:

Selected cash flow data	Nine Months Ended September 30,	
	2025	2024
Cash provided by (used in):	(In thousands)	
Operating activities	\$ 222,048	\$ 144,259
Investing activities	(22,016)	(60,297)
Financing activities	(6,034)	(8,255)

Operating Activities

Net cash provided by operating activities for the nine months ended September 30, 2025, primarily consisted of net income of \$136.2 million adjusted for non-cash items of \$34.7 million related to stock-based compensation expense, \$30.0 million related to acquired IPR&D, \$17.9 million related to intangible amortization and depreciation, offset by \$14.7 million related to deferred tax assets. Net working capital excluding cash decreased by \$17.8 million, primarily driven by increases in accounts receivable due to higher net product revenue in the current period, offset by an increase in accounts payable due to the timing of payments and an increase in accrued expenses primarily from higher accrued rebates.

Net cash provided by operating activities for the nine months ended September 30, 2024, primarily consisted of net income of \$96.0 million adjusted for non-cash items of \$42.6 million related to acquired IPR&D, \$32.9 million related to stock-based compensation expense, and \$18.1 million related to intangible amortization and depreciation, offset by \$22.6 million related to deferred tax assets. Net working capital excluding cash increased by \$23.1 million, primarily driven by increases in accounts receivable due to higher net product revenue in the current period and decreases in accounts payable due to the timing of payments.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2025, was \$22.0 million, which was primarily attributable to \$67.3 million in purchases of debt securities, a \$15.0 million upfront fee paid to CiRC and \$0.2 million in purchases of property and equipment, partially offset by \$60.5 million from maturities of investments.

Net cash used in investing activities for the nine months ended September 30, 2024, was \$60.3 million, which was primarily attributable to \$69.6 million in purchases of debt securities, a \$25.5 million license fee paid to Bioprojet, \$33.1 million net cash consideration paid for the acquisition of Epygenix, and \$0.6 million in purchases of property and equipment, partially offset by \$68.5 million from maturities of investments.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2025, was \$6.0 million, which primarily consisted of \$11.3 million in principal payments associated with the TLA Credit Agreement and \$2.3 million of employee withholding tax payments related to stock-based awards, partially offset by \$7.6 million in proceeds from the exercise of stock options.

Net cash used in financing activities for the nine months ended September 30, 2024, was \$8.3 million, which primarily consisted of \$11.3 million in principal payments associated with the TLA Credit Agreement, partially offset by \$3.2 million in proceeds from the exercise of stock options, and \$0.3 million of employee withholding tax payments related to stock-based awards.

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, the measurement of compensation expense pursuant to stock-based awards, the calculation of our income tax provision, and the determination of accounting treatment for our business combinations. 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 \$685.2 million of investments in money market funds, U.S. treasury notes, corporate bonds and municipal obligations as of September 30, 2025, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of September 30, 2025, we had \$170.0 million in borrowings outstanding. The Term Loan bears 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 \$170.0 million of principal outstanding as of September 30, 2025, an immediate 10% change in the Term 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 may affect us by potentially increasing costs such as labor and our 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 September 30, 2025, and 2024.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2025. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2025, 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.

Refer to Part I, Item I, Note 13 "Commitments and Contingencies," of this Quarterly Report for a full description of our material pending legal matters.

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, 2024, 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 August 13, 2025, Sandip Kapadia, Chief Financial Officer and Chief Administrative 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 (i) up to 50,000 shares of the Company's common stock related to the exercise of options, (ii) up to 20,961 shares of the Company's common stock related to the September 30, 2025 vesting of restricted stock units previously granted, and (iii) an indeterminable number of shares of the Company's common stock that will depend on the number of shares sold to cover tax withholding obligations in connection with the vesting of 8,538 restricted stock units previously granted, beginning on January 15, 2026 and continuing until June 30, 2026.

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 Zynerva 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
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, 2025, 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 Data 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: November 4, 2025

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer and Chief Administrative
Officer (principal financial officer)
Date: November 4, 2025

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: November 4, 2025

By: /s/ Jeffrey M. Dayno
Jeffrey M. Dayno
President, Chief Executive Officer and Director
(Principal Executive Officer)

Certification of Principal Financial Officer

I, Sandip Kapadia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2025

By: /s/ Sandip Kapadia

Sandip Kapadia

Chief Financial Officer and Chief Administrative Officer

(Principal Financial Officer and Principal Accounting Officer)

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

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the quarter ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2025

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.
