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

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2021

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)

630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA

(Address of principal executive offices)

82-2279923

(I.R.S. Employer
Identification No.)

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:

[Table of Contents](#)

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 May 4, 2021, there were 56,900,991 shares of the registrant's common stock, par value \$0.00001 value per share, outstanding.

TABLE OF CONTENTS

	<u>Page</u>
Part I. Financial Information	4
Item 1. Financial Statements	4
Condensed Consolidated Balance Sheets (Unaudited)	4
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (Unaudited)	5
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited)	6
Condensed Consolidated Statements of Cash Flows (Unaudited)	7
Notes to Condensed Consolidated Financial Statements (Unaudited)	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3. Quantitative and Qualitative Disclosures About Market Risk	36
Item 4. Controls and Procedures	36
Part II. Other Information	37
Item 1. Legal Proceedings	37
Item 1A. Risk Factors	37
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 3. Defaults upon Senior Securities	37
Item 4. Mine Safety Disclosures	37
Item 5. Other Information	37
Item 6. Exhibits	38
Signatures	40

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 141,169	\$ 228,631
Trade receivables, net	23,615	22,176
Inventory, net	4,405	3,823
Prepaid expenses	7,089	6,959
Other current assets	1,466	1,302
Total current assets	<u>177,744</u>	<u>262,891</u>
NONCURRENT ASSETS:		
Property and equipment, net	842	938
Restricted cash	750	750
Intangible assets, net	157,764	162,343
Other noncurrent assets	152	152
Total noncurrent assets	<u>159,508</u>	<u>164,183</u>
TOTAL ASSETS	\$ 337,252	\$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 4,391	\$ 2,556
Accrued compensation	4,523	8,942
Accrued expenses	24,261	122,727
Other current liabilities	262	314
Total current liabilities	<u>33,437</u>	<u>134,539</u>
NONCURRENT LIABILITIES:		
Deferred rent	192	212
Long term debt, net	194,913	194,250
Other noncurrent liabilities	831	893
Total noncurrent liabilities	<u>195,936</u>	<u>195,355</u>
TOTAL LIABILITIES	229,373	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.00001 par value; 10,000,000 shares and 0 shares authorized at March 31, 2021 and December 31, 2020, respectively; 0 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock—\$0.00001 par value; 500,000,000 shares authorized at March 31, 2021 and December 31, 2020, respectively; 56,892,406 shares and 56,890,569 issued and outstanding at March 31, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	588,687	585,374
Accumulated deficit	<u>(480,809)</u>	<u>(488,195)</u>
TOTAL STOCKHOLDERS' EQUITY	107,879	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 337,252	\$ 427,074

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Net product revenues	\$ 59,674	\$ 19,840
Cost of product sold	10,409	3,474
Gross profit	49,265	16,366
Operating expenses:		
Research and development	4,679	3,431
Sales and marketing	15,506	13,254
General and administrative	14,547	9,290
Total operating expenses	34,732	25,975
Operating income (loss)	14,533	(9,609)
Loss on debt extinguishment	—	(22,639)
Other expense, net	(20)	—
Interest expense, net	(7,127)	(6,372)
Income (loss) before income taxes	7,386	(38,620)
Income taxes	—	—
Net income (loss) and comprehensive income (loss)	\$ 7,386	\$ (38,620)
Accumulation of dividends on preferred stock	—	(10,445)
Net income (loss) available to common stockholders	\$ 7,386	\$ (49,065)
EARNINGS (LOSS) PER SHARE:		
Basic	\$ 0.13	\$ (6.30)
Diluted	\$ 0.13	\$ (6.30)
Weighted average number of shares of common stock - basic	56,891,451	7,790,667
Weighted average number of shares of common stock - diluted	58,805,285	7,790,667

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share and per share data)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance as of December 31, 2020	56,890,569	\$ 1	\$ 585,374	\$ (488,195)	\$ 97,180
Net income	—	—	—	7,386	7,386
Exercise of stock options	1,837	—	12	—	12
Stock-based compensation	—	—	3,301	—	3,301
Balance as of March 31, 2021	56,892,406	\$ 1	\$ 588,687	\$ (480,809)	\$ 107,879

	Convertible Preferred Stock Series A, B, & C		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2019	318,510,205	\$ 411,275	7,787,470	\$ —	\$ —	\$ (422,862)	\$ (422,862)
Net loss	—	—	—	—	—	(38,620)	(38,620)
Preferred stock dividend, Series A	—	8,844	—	—	(519)	(8,325)	(8,844)
Preferred stock accretion, Series A	—	776	—	—	—	(776)	(776)
Preferred stock dividend, Series B	—	302	—	—	—	(302)	(302)
Preferred stock accretion, Series B	—	6	—	—	—	(6)	(6)
Preferred stock dividend, Series C	—	1,299	—	—	—	(1,299)	(1,299)
Preferred stock accretion, Series C	—	140	—	—	—	(140)	(140)
Exercise of stock options	—	—	18,378	—	151	—	151
Stock-based compensation	—	—	—	—	368	—	368
Balance as of March 31, 2020	318,510,205	\$ 422,642	7,805,848	\$ —	\$ —	\$ (472,330)	\$ (472,330)

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

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	\$ 7,386	\$ (38,620)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	100	97
Intangible amortization	4,579	1,786
Stock-based compensation expense	3,301	368
Stock appreciation rights market adjustment	(50)	107
Warrant expense	—	1,146
Debt issuance costs amortization	664	340
Loss on debt extinguishment	—	22,639
Change in operating assets and liabilities:		
Trade receivables	(1,439)	(7,053)
Inventory	(582)	(783)
Prepaid expenses and other assets	(296)	(4,111)
Other non-current assets	—	732
Trade payables	1,835	(1,509)
Accrued expenses and other current liabilities	(2,936)	(1,929)
Other non-current liabilities	(32)	88
Net provided by (cash used) in operating activities	<u>12,530</u>	<u>(26,702)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4)	—
Milestone and acquisition of intangible asset	(100,000)	—
Net cash used in investing activities	<u>(100,004)</u>	<u>—</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from long term debt	—	200,000
Debt issuance costs	—	(5,804)
Extinguishment of debt	—	(102,538)
Extinguishment of debt exit fees	—	(18,047)
Proceeds from exercised options	12	151
Net cash provided by financing activities	<u>12</u>	<u>73,762</u>
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	<u>(87,462)</u>	<u>47,060</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	229,381	25,207
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	<u>\$ 141,919</u>	<u>\$ 72,267</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	\$ 6,510	\$ 6,214
Cash paid during the year for milestones	100,000	—
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Series A Preferred Stock accrued return	—	8,844
Series A accretion of issuance costs	—	776
Series B Preferred Stock accrued return	—	302
Series B accretion of issuance costs	—	6
Series C Preferred Stock accrued return	—	1,299
Series C accretion of issuance costs	—	140
Warrant financing	—	2,359

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

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

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

The Company

Our operating subsidiary, Harmony Biosciences, LLC (“Harmony”), was formed on May 17, 2017. Harmony Biosciences Holdings, Inc. (the “Company”) was founded on July 25, 2017 as Harmony Biosciences II, LLC, a Delaware limited liability company, and the Company converted to a Delaware corporation named Harmony Biosciences II, Inc. on September 19, 2017. On February 3, 2020, the Company changed its name to Harmony Biosciences Holdings, Inc. The Company is a holding company and has no operations. The Company’s operations are conducted in its wholly owned subsidiary, Harmony. The Company is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

Initial Public Offering

On August 21, 2020, the Company completed its initial public offering (“IPO”) of common stock, in which it sold 6,151,162 shares, including 802,325 shares pursuant to the underwriters’ over-allotment option. The shares began trading on the Nasdaq Global Market on August 19, 2020. The shares were sold at an IPO price of \$24.00 per share for net proceeds of approximately \$135,435, after deducting underwriting discounts and commissions and offering expenses of approximately \$12,193 payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company’s convertible preferred stock were automatically converted into shares of common stock and the accrued dividend payable to holders of the convertible preferred stock was paid out in shares of common stock, resulting in a total of 42,926,630 shares of common stock being issued to former holders of the Company’s convertible preferred stock. Warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for a total of 410,239 shares of common stock.

Reverse Stock Split

On August 11, 2020, the Company implemented a 1-for-8.215 reverse stock split of the Company’s common stock. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company’s Preferred Stock and preferred dividend were proportionately reduced. All references in the accompanying condensed consolidated financial statements and related notes to the number of shares of common stock, convertible preferred stock, warrants and options to purchase common stock and per share data reflect the effect of the reverse stock split.

2. LIQUIDITY AND CAPITAL RESOURCES

The unaudited condensed consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has an accumulated deficit of \$480,809 and \$488,195, as of March 31, 2021 and December 31, 2020, respectively. As of March 31, 2021, the Company had cash and cash equivalents of \$141,169.

On August 21, 2020, the Company received aggregate proceeds from a common stock offering of approximately \$135,435, net of underwriting discounts and commissions and other estimated offering expenses (see Note 11). Additionally, on January 9, 2020, the Company received aggregate proceeds of approximately \$200,000 through the loan agreement with OrbiMed Royalty & Credit Opportunities, L.P. This capital raise and debt issuance has resolved the Company’s significant risks and uncertainties regarding sources of liquidity, which previously raised substantial doubt about the Company’s ability to continue as a going concern.

The Company believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented. All intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated balance sheet as of March 31, 2021, and the condensed consolidated statements of cash flows for the three months ended March 31, 2021 and 2020, and condensed consolidated statements of operations and comprehensive income (loss) and the condensed consolidated statements of convertible preferred stock and shareholders’ equity (deficit) for the three months ended March 31, 2021 and 2020, are unaudited. The balance sheet as of December 31, 2020 was derived from audited financial statements as of and for the year ended December 31, 2020. 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, 2020, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statements of the Company’s financial position as of March 31, 2020, and the results of its operations and its cash flows for the three months ended March 31, 2021 and 2020. The condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and note disclosures of the Company normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC’s rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto for the year ended December 31, 2020. The balance sheet data as of December 31, 2020 was derived from the Company’s audited financial statements for the year ended December 31, 2020.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosures in the Condensed Consolidated Financial Statements, including the notes thereto, and elsewhere in this report. Uncertainties related to the magnitude and duration of COVID-19, the extent to which it will impact our estimated future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending and health insurance coverage, the speed of the anticipated recovery and governmental and business reactions to the pandemic have increased the complexity of developing these estimates, including the carrying amounts of long-lived assets, and the intangible asset. Actual results may differ significantly from our estimates, including as a result of COVID-19.

Fair Value of Financial Instruments

The Company’s unaudited condensed consolidated financial statements include cash, cash equivalents, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value. Additionally, prior to the IPO, the Company’s condensed consolidated financial statements included a warrant liability that was carried at fair value and was re-measured at each balance sheet date until it would be exercised or expired. In connection with the IPO, the Warrants were re-evaluated under the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 480 *Distinguishing Liabilities from Equity* and reclassified to equity. See Note 13 for a further discussion of the warrants.

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

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

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

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

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

Cash, Cash Equivalents and Restricted Cash

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

	As of	
	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 141,169	\$ 228,631
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	<u>\$ 141,919</u>	<u>\$ 229,381</u>

Amounts included in restricted cash represent those amounts required to be held as a security deposit in the form of letters of credit for the Company's credit card program and the fleet program.

Concentrations of Risk

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

The Company is also subject to credit risk from its trade receivables related to its product sales. The Company monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to specialty pharmaceutical distribution companies within the United States. Customer creditworthiness is monitored and collateral is not required. Historically, the Company has not experienced credit losses on its accounts receivable. As of March 31, 2021, three customers accounted for 100% of gross accounts receivable, Caremark LLC ("CVS Caremark"), which accounted for 34% of gross accounts receivable; PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 36% of gross accounts receivable; and Accredo Health Group, Inc. ("Accredo"), which accounted for 30% of gross accounts receivable. As of December 31, 2020, three customers accounted for 100% of gross accounts receivable, CVS Caremark, which accounted for 44% of gross accounts receivable; Pantherx, which accounted for 23% of gross accounts receivable; and Accredo, which accounted for 33% of gross accounts receivable.

For the three months ended March 31, 2021, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 35% of gross product revenues; Pantherx accounted for 38% of gross product revenues; and Accredo accounted for 27% of gross product revenues. For the three months ended March 31, 2020 three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 42% of

gross product revenues; Pantherx accounted for 35% of gross product revenues; and Accredo accounted for 23% of gross product revenues.

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

Cost of Product Sold

Cost of product sold includes manufacturing and distribution costs, the cost of drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, and salaries of employees involved with production. The Company began capitalizing inventory upon FDA approval of WAKIX®. Excluded from cost of product sold shown and included in general and administrative expenses on the condensed consolidated statements of operations and comprehensive loss is amortization of acquired developed technology of \$4,579 and \$1,786 for the three months ended March 31, 2021 and 2020, respectively.

Advertising Expenses

We expensed the costs of advertising, including promotional expenses, as incurred. Advertising expense was \$1,653 and \$2,454 for the three months ended March 31, 2021 and 2020, respectively.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued amended guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities in the balance sheet and disclosing key information about leasing arrangements. The new guidance clarifies the criteria for distinguishing between a finance lease and operating lease, as well as classification between the two types of leases, which is substantially unchanged from the previous lease guidance. Further, the new guidance requires a lessee to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset, initially measured at the present value of the lease payments. For finance leases, a lessee should recognize interest on the lease liability separately from amortization of the right-of-use asset. For operating leases, a lessee should recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election not to recognize lease assets and lease liabilities. The new standard will become effective for the Company's fiscal year ending December 31, 2022. The Company is currently assessing the impact of this amended guidance and the timing of adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 for companies deemed to be small reporting companies as of November 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact of adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual reporting periods beginning after December 15, 2020 with early adoption permitted. The Company is currently evaluating the impact of adopting this new accounting guidance.

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

4. INVENTORY

Inventory, net consisted of the following:

	As of	
	March 31, 2021	December 31, 2020
Raw materials	\$ 773	\$ 396
Work in process	1,585	2,660
Finished goods	2,356	941
Inventory, gross	4,714	3,997
Reserve for obsolescence	(309)	(174)
Total inventory, net	<u>\$ 4,405</u>	<u>\$ 3,823</u>

5. INTANGIBLE ASSETS

On August 15, 2019, the Company received FDA approval of WAKIX (pitolisant) for the treatment of excessive daytime sleepiness (“EDS”) in adult patients with narcolepsy. This event triggered a milestone payment of \$75,000 associated with the License Agreement (discussed below) which the Company capitalized as an intangible asset and paid in November of 2019. The Company determined a useful life of 10 years for such intangible asset, and, as of December 31, 2020 the remaining useful life was 8.5 years. Prior to this event, all other milestones associated with the License Agreement were expensed through research and development as they did not meet the criteria to be recognized as an intangible asset.

On October 13, 2020, the Company received notice that the FDA approved 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 associated with the License Agreement which the Company capitalized as an intangible asset and paid in January of 2021. The Company determined a useful life of 9 years for such intangible asset, and, as of December 31, 2020 the remaining useful life was 8.5 years. Amortization expense for the three months ended March 31, 2021 and 2020 was \$4,579 and \$1,786, respectively and is recorded in general and administrative expenses on the condensed consolidated statements of operations and comprehensive income (loss).

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

Years ending December 31,	
2021 (excluding the three months ended March 31, 2021)	\$ 13,927
2022	18,569
2023	18,569
2024	18,569
2025	18,569
Total	<u>\$ 88,203</u>

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

	As of	
	March 31, 2021	December 31, 2020
Gross Carrying Amount	\$ 175,000	\$ 175,000
Accumulated Amortization	(17,236)	(12,657)
Net Book Value	<u>\$ 157,764</u>	<u>\$ 162,343</u>

6. LICENSE AGREEMENT

On July 28, 2017, Harmony entered into the License Agreement (“the License Agreement”) with Bioprojet Société Civile de Recherche (“Bioprojet”) whereby Harmony acquired the exclusive right to commercialize the pharmaceutical compound pitolisant for the treatment, and/or prevention, of narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, and Parkinson’s disease as well as any other indications unanimously agreed by the parties in the United States and its territories. A milestone payment of \$50,000 was due upon acceptance by the FDA of pitolisant’s NDA, which was achieved on February 12, 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 on August 14, 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. An additional \$40,000 milestone payment is due to Bioprojet upon WAKIX attaining \$500,000 in aggregate net sales in the United States. The License Agreement also requires sales-based milestone payments, a fixed trademark royalty and a tiered royalty, all based on net sales, which become due and payable to Bioprojet on a quarterly basis. During the three months ended March 31, 2021 and 2020, the Company incurred \$9,547 and \$3,277, respectively, for sales-based, trademark and tiered royalties recognized as cost of product sold. As of March 31, 2021 and December 31, 2020, the Company had accrued \$9,512 and \$9,006, respectively, for sales-based, trademark and tiered royalties. At December 31, 2020, the Company had accrued \$100,000 for the milestone payment to Bioprojet.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	March 31, 2021	December 31, 2020
Royalties due to third parties	9,512	9,006
Rebates and other sales deductions	9,492	7,803
Selling and marketing	1,891	1,905
Professional fees, consulting, and other services	1,478	1,081
Other expenses	1,006	746
Research and development	882	2,186
Milestone payment	\$ —	\$ 100,000
	<u>\$ 24,261</u>	<u>\$ 122,727</u>

8. DEBT**Credit Agreements**

On February 28, 2019, the Company entered into a multi-draw loan agreement with CRG Servicing LLC for an aggregate of \$200,000 (the “CRG Loan”), which would have matured in March 2025. The CRG Loan bore a fixed rate of 12%. The CRG Loan required compliance with certain financial covenants. The Company could draw three tranches of the CRG Loan based on achieving specific milestones and dates. The Company could elect to pay the interest on the outstanding principal amount as follows: (i) only 7.5% of the 12% per annum in cash, paid quarterly, starting in March 2019, and (ii) 4.5% of the 12% per annum interest as compounded interest, added to the aggregate outstanding principal balance quarterly; the amount of any such compounded interest being a paid-in-kind loan.

As of December 31, 2019, the Company had borrowed \$100,000, resulting in cash proceeds received of \$94,816, net of issuance costs. The issuance costs of \$5,184 were being amortized over the six-year loan term of the CRG Loan.

On January 9, 2020, the Company entered into a credit agreement with OrbiMed Royalty & Credit Opportunities, LP for an aggregate amount of \$200,000 (the “OrbiMed Loan”), which matures in January 2026. Borrowings under the OrbiMed Loan are collateralized by all of the Company’s assets, excluding the

intellectual property licensed through the License Agreement. The OrbiMed Loan bears an interest rate equal to the sum of (i) the greater of (a) 1-month LIBOR or (b) 2.00% per annum, plus (ii) 11.00% per annum, paid in cash monthly in arrears on the last day of each month starting in January 2020. At the time of prepayment or repayment of all or any portion of the principal of the OrbiMed Loan, the Company is required to pay an exit fee of 7.0% of the principal amount of the OrbiMed Loan prepaid, repaid, or required to be prepaid or repaid. The Company recorded the exit fee as a liability and debt discount at the origination of the term loan.

In addition to entering into the OrbiMed Loan, the Company extinguished the CRG Loan which required a payoff amount of \$120,893 consisting of principal repayment, interest, and exit fees. In connection with extinguishment of the CRG Loan, we recognized a loss on extinguishment of \$22,639, which included an exit fee of \$18,047 and the write-off of the remaining unamortized debt issuance costs of \$4,592. The loss on extinguishment of debt was recorded in loss on debt extinguishment within the Company's condensed consolidated statements of operations. The net cash received as a result of the transaction, less debt issuance costs of \$5,804, was \$73,313. These debt issuance costs will be amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. The fair value of the OrbiMed loan as of March 31, 2021 was \$260,328.

In connection with the OrbiMed Loan, the Company issued warrants (the "Warrants") to OrbiMed Royalty & Credit Opportunities, LP on January 9, 2020. See Note 13 for further discussion of the Warrants. Pursuant to the Warrants, OrbiMed Royalty & Credit Opportunities, LP, may purchase up to 410,239 shares of the Company's Common Stock for an initial exercise price of \$16.10 at any time from the date of execution of the Warrants through the expiration date, defined within the Warrants as the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization. The fair value of the Warrants using the Black-Scholes option-pricing model was \$2,359 at January 9, 2020. The portion of the OrbiMed Loan proceeds allocated to the warrant liability resulted in a debt discount, which is presented in the condensed consolidated balance sheets as a direct deduction from the carrying value of the debt and is being amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. The unamortized debt discount as of March 31, 2021 is \$2,031 and is presented in the condensed consolidated balance sheets as a direct deduction from the carrying value of the debt.

The balances of the OrbiMed Loan as of March 31, 2021 and December 31, 2020 were as follows:

	March 31, 2021	December 31, 2020
Liability component - principal	\$ 200,000	\$ 200,000
Exit fee	14,000	14,000
Unamortized debt discount associated with the exit fee, debt financing costs and discount with warrant financing	(19,087)	(19,750)
Liability component - net carrying value	<u>\$ 194,913</u>	<u>\$ 194,250</u>

Interest expense related to the OrbiMed Loan and CRG Loan were included in interest expense, net in the Condensed Consolidated Statements of Operations as follows:

	For the Three Months Ended March 31,	
	2021	2020
Interest on principal balance	\$ 6,510	\$ 6,214
Amortization of deferred financing costs	664	340
Total term loan interest expense	<u>\$ 7,174</u>	<u>\$ 6,554</u>

9. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company is subject to claims and suits arising in the ordinary course of business. The Company accrues such liabilities when they are known, if they are deemed probable and can be reasonably estimated.

Lease Agreements

In April 2018, the Company entered into an operating lease for approximately nine thousand square feet of office space in Northbrook, IL, which expired in January 2020.

In June 2018, the Company entered into an operating lease for approximately fifteen thousand square feet of office space in Plymouth Meeting, PA, which expires in May 2024.

In December 2020, the Company entered into an operating lease for approximately thirteen thousand square feet of additional office space in Plymouth Meeting, PA, which expires in May 2024. The term will not commence until the Company takes occupancy in mid-2021.

The terms of the lease payments provide for rental payments on a monthly basis and on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. In addition, tenant improvement allowances recorded are amortized as a reduction to rent expense on a straight-line basis over the lease term. Rent expense was \$136 for the three months ended March 31, 2021, compared to \$204 for the three months ended March 31, 2020. The following table sets forth the lease payment obligations as of March 31, 2021, for the periods indicated below:

Years ending December 31,	
2021 (excluding the three months ended March 31, 2021)	\$ 401
2022	875
2023	892
2024	334
2025	—
Thereafter	—
Total	\$ 2,502

10. CONVERTIBLE PREFERRED STOCK

Upon the closing of the IPO, all outstanding shares of the Company's convertible preferred stock were automatically converted into shares of common stock and the accrued dividend payable to holders of the convertible preferred stock was paid out in shares of common stock, resulting in a total of 42,926,630 shares of common stock being issued to former holders of the Company's convertible preferred stock.

Series A Preferred Stock

On September 22, 2017, the Company issued 270,000,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$270,000 in the aggregate. On January 8, 2018, the Company issued an additional 15,000,000 shares of Series A convertible preferred stock for a purchase price of \$1.00 per share, or \$15,000 in the aggregate. As of March 31, 2020, there were 286,000,000 Series A convertible preferred stock authorized of which 285,000,000 were issued and outstanding. Each outstanding share of Series A convertible preferred stock accrued dividends at 10% per annum of the Series A original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series A convertible preferred stock were cumulative and were compounded annually.

Series B Preferred Stock

On January 8, 2018, the Company issued 8,000,000 shares of Series B convertible preferred stock for a purchase price of \$1.25 per share, or \$10,000 in the aggregate. As of March 31, 2020, there were 8,030,000 shares of Series B convertible preferred stock authorized, of which 8,000,000 were issued and outstanding. Each outstanding share of Series B convertible preferred stock accrued dividends at 10% per annum of the Series B original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series B convertible preferred stock were cumulative and were compounded annually.

Series C Preferred Stock

On August 9, 2019, the Company issued 25,510,205 shares of Series C convertible preferred stock for a purchase price of \$1.96 per share, or \$50,000 in the aggregate. As March 31, 2020, there were 25,600,000 shares of Series C convertible preferred stock authorized, of which 25,510,205 were issued and outstanding. Each outstanding share of Series C convertible preferred stock accrued dividends at 10% per annum of the Series C original issue price, subject to adjustment for stock splits, combinations, recapitalizations, stock dividends and similar transactions. Preferred dividends on the Series C convertible preferred stock were cumulative and were compounded annually.

Dividends

The holders of Series A, Series B, and Series C convertible preferred stock were entitled to receive, when and if declared by the board of directors of the Company, cumulative dividends equal to a 10% per annum of Series A, Series B, and Series C convertible preferred stock. In addition, the holders of the outstanding shares of Series A, Series B, and Series C convertible preferred stock were entitled to receive, when and if declared by the board of directors of the Company, a dividend at least equal to any dividend payable on the Company's common stock as if all convertible preferred stock had been converted to common stock. No dividends were declared as of December 31, 2019. As part of the Company's IPO, the Company's accrued cumulative dividend was paid out to holders of Series A, Series B, and Series C convertible preferred stock in shares of the Company's common stock and reflects the reverse stock split in connection with the mandatory conversion of the Series A, Series B, and Series C convertible preferred stock into shares of the Company's common stock.

11. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

On August 11, 2020, the Company implemented a 1-for-8.215 reverse stock split of the Company's common stock. All share and per share data shown in the accompanying financial statements and related notes have been retroactively revised to reflect the reverse stock split with the exception of the preferred stock. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's Preferred Stock were proportionately reduced. As of August 11, 2020, all outstanding shares of preferred stock and preferred stock dividend were convertible into shares of common stock on a 1-for-8.215 basis. On August 21, 2020, the Company completed its IPO of common stock, in which it sold 6,151,162 shares, including 802,325 shares pursuant to the underwriters' over-allotment option. The shares began trading on the Nasdaq Global Market on August 19, 2020. The shares were sold at an IPO price of \$24.00 per share for net proceeds of approximately \$135,435, after deducting underwriting discounts and commissions and offering expenses of approximately \$12,193 incurred by the Company.

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

12. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

Stock Incentive Plan

On August 7, 2017, the Company adopted an equity incentive plan (the "2017 Plan"). Under the 2017 Plan, directors, officers, employees, consultants, and advisors of the Company can be paid incentive compensation measured by the value of the Company's common shares through grants of stock options, stock appreciation rights ("SARs"), or restricted stock.

In connection with the Company’s IPO, the board of directors adopted, and its stockholders approved, the 2020 Incentive Award Plan (the “2020 Plan”), in order to facilitate the grant of cash and equity incentives to directors, employees (including the Company’s named executive officers) and consultants of the Company and its subsidiaries. Upon the effectiveness of the 2020 Plan, no further grants 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. The 2020 Plan provides for the grant of stock options, including incentive stock options (“ISOs”) and non-qualified stock options (“NSOs”), SARs, restricted stock, dividend equivalents, restricted stock units (“RSUs”) and other stock or cash-based awards.

Stock options and stock appreciation rights under the 2017 Plan and 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).

Changes in stock options granted under the 2017 and 2020 Plans for the three months ended March 31, 2021 is as follows:

	Number of Awards	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Awards outstanding—December 31, 2020	5,210,832	\$ 17.66	8.63
Awards issued	1,112,606	\$ 35.44	
Awards exercised	(1,837)	\$ 8.22	
Awards forfeited	(55,690)	\$ 8.22	
Awards outstanding—March 31, 2021	<u>6,265,911</u>	\$ 20.90	8.65

Changes in SARs granted under the 2017 Plan for the three months ended March 31, 2021 is as follows:

	Number of Awards	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Awards outstanding—December 31, 2020	49,294	\$ 9.24	8.29
Awards issued	—	\$ —	
Awards exercised	—	\$ —	
Awards forfeited	—	\$ —	
Awards outstanding—March 31, 2021	<u>49,294</u>	\$ 9.24	8.04

Changes in RSUs granted under the 2020 Plan for the three months ended March 31, 2021 is as follows:

	Number of Awards	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Awards outstanding—December 31, 2020	—	\$ —	—
Awards issued	60,000	\$ 29.03	
Awards exercised	—	\$ —	
Awards forfeited	—	\$ —	
Awards outstanding—March 31, 2021	<u>60,000</u>	\$ 29.03	10.00

As of March 31, 2021 and December 31, 2020, stock awards issued under the 2017 and 2020 Plans of 1,143,791 and 987,538 common shares, respectively, were vested. The Company has elected early adoption of ASU No. 2016-09 to recognize forfeitures as they occur. As a result of the adoption, for the three months ended March 31, 2020 the Company reversed \$10 out of stock-based compensation previously recorded.

Value of Stock Options and SARs

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

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

	As of	
	March 31, 2021	December 31, 2020
Dividend yield	0.00 %	0.00 %
Expected volatility	60.00 %	55.00 - 95.80 %
Risk-free interest rate	0.66 - 1.19 %	0.32 - 0.56 %
Lack of marketability discount	0.00 %	0.00 - 20.48 %
Expected term (years)	4.9 - 6.3	5.4 - 6.5

Value of RSUs

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

The weighted average per share fair value of awards issued under the 2017 Plan and 2020 Plan was \$11.99 and \$10.06 on March 31, 2021 and December 31, 2020, respectively.

Stock-based compensation expense, net was \$3,251 and \$475 for the three months ended March 31, 2021 and 2020, respectively, and was recorded in the condensed consolidated statements of operations and comprehensive loss in the following line items:

	For the Three Months Ended March 31,	
	2021	2020
Research and development expense	\$ 420	\$ 80
Sales and marketing expense	620	108
General and administrative expense	2,211	287
	<u>\$ 3,251</u>	<u>\$ 475</u>

Options and RSUs issued under the 2017 Plan and 2020 Plan are reflected as a component of equity in these condensed consolidated financial statements. Stock appreciation rights are reflected as other non-current liability. The Company will recognize compensation expense for these awards as summarized in the following table.

Years Ending December 31,	Stock Compensation Expense
2021 (excluding the three months ended March 31, 2021)	\$ 12,920
2022	16,867
2023	15,880
2024	14,900
2025	5,831

13. WARRANTS

In connection with the OrbiMed Loan, the Company issued Warrants to OrbiMed Royalty & Credit Opportunities, LP on January 9, 2020. Pursuant to the Warrants, OrbiMed Royalty & Credit Opportunities, LP, may purchase up to 410,239 shares of the Company's Common Stock for an initial exercise price of \$16.10 at any time from the date of execution of the Warrants through the expiration date, defined within the Warrants as the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization. The fair value of the Warrants using the Black-Scholes option-pricing model was \$2,359 on January 9, 2020 and was initially recorded as a warrant liability which was included in warrant liability in the condensed consolidated balance sheet. The portion of the OrbiMed Loan proceeds allocated to the warrant liability resulted in a debt discount, which is presented in the condensed consolidated balance sheets as a direct deduction from the carrying value of the debt and is being amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. The unamortized debt discount as of March 31, 2021 and December 31, 2020 was \$2,031 and \$2,102, respectively, and is presented in the condensed consolidated balance sheet as a direct deduction from the carrying value of the debt. During the three months ended March 31, 2020, a loss of \$1,146 was recorded in other expense in the condensed consolidated statements of operations due to the change in the fair value of the warrant liability. See Note 15 for the fair value of the Warrants.

In connection with the IPO, the financial instrument underlying the warrants was converted from the Company's Series C Preferred Stock to the Company's Common Stock. As a result of this conversion the Warrants were re-evaluated under ASC 480 Distinguishing Liabilities from Equity and ASC 815 Derivatives and Hedging and reclassified to equity.

14. EARNINGS PER SHARE

For the three months ended March 31, 2020, the Company used the two-class method to compute net loss per common share because the Company has issued securities (convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by the amount of any dividends earned and the accretion of convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of convertible preferred stock to the extent that each preferred security may share in the earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

The Company has reported a net loss for the three months ended March 31, 2020, and the weighted average number of shares utilized for basic and diluted net loss per share attributable to common stockholders are the same for these periods because all convertible preferred stock and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact. Additionally, the fair value adjustment for the warrants was excluded from the computation of diluted net loss for the three months ended March 31, 2020 since the additional income would have an antidilutive impact.

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

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

	For the Three Months Ended March 31,	
	2021	2020
Numerator		
Net income (loss)	\$ 7,386	\$ (38,620)
Accumulation of dividends on preferred stock	—	(10,445)
Net income (loss) available to common shareholders	\$ 7,386	\$ (49,065)
Denominator		
Net income (loss) per common share - basic	\$ 0.13	\$ (6.30)
Net income (loss) per common share - diluted	\$ 0.13	\$ (6.30)
Weighted average number of shares of common stock - basic	56,891,451	7,790,667
Weighted average number of shares of common stock - diluted	58,805,285	7,790,667

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

	For the Three Months Ended March 31,	
	2021	2020
Stock options, SARs, and RSUs to purchase common stock	1,691,882	—
Warrants	221,953	—
Total	1,913,835	—

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

	For the Three Months Ended March 31,	
	2021	2020
Stock options, SARs, and RSUs to purchase common stock	4,683,323	2,413,507
Convertible preferred stock	—	39,141,451
Warrants	188,286	410,239
Total	4,871,609	41,965,197
Adjustment for warrants	\$ —	\$ 1,146

15. FINANCIAL INSTRUMENTS

The Company primarily applies the market approach to determine the fair value of financial instruments that are measured at fair value on a recurring basis. There were no changes to its valuation techniques used to determine the fair value of financial instruments during the three months ended March 31, 2021. The Company's financial assets and liabilities which are measured at fair value on a recurring basis were comprised of cash, cash equivalents, and restricted cash of \$141,919 and \$229,381 as of March 31, 2021 and December 31, 2020, respectively, based on Level 1 inputs.

The Company estimates the fair value of the warrant liability using the Black-Scholes option-pricing model at each balance sheet date or when specific events occur. As discussed in Note 13, in connection with the Company's IPO the warrant fair value was updated on August 19, 2020 with the change in fair value recorded in current period earnings as other expense in the condensed consolidated statement of operations and reclassified to equity. During the three months ended March 31, 2020, a loss of \$1,146 was recorded in general and administrative expense in the condensed consolidated statements of operations due to the change in the fair value of the warrant liability.

16. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon Biosciences, LLC (“Paragon”). The related party is an entity that shares common ownership with the Company. In addition, the Chairman of the Company’s board of directors was the President and owner of the entity. For the three months ended March 31, 2021 and 2020, respectively, the Company incurred \$71 and \$1,730, respectively, in management fee expense and other expenses to this related party, which are included in general and administrative expense in the condensed consolidated statements of operations and comprehensive loss. The Company terminated the Management Services Agreement upon the consummation of its IPO. The Company is also party to a right of use agreement with the related party whereby it has access to and the right to use certain office space leased by the related party in Chicago, Illinois. In addition, the Company had participated in certain transactions with separate related parties that also share common ownership with the Company, primarily related to combined employee health plans. As of March 31, 2021 and December 31, 2020, respectively, the amounts from related parties included in prepaid expenses and other assets was \$23 and \$1, respectively.

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

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, the anticipated impact of the novel coronavirus ("COVID-19") pandemic on our business, business strategy, products, prospective products, product approvals, research and development costs, anticipated timing and likelihood of success of clinical trials, expected timing of the release of clinical trial data, the plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, statements about:

- our commercialization efforts and strategy for WAKIX;
- the rate and degree of market acceptance and clinical utility of WAKIX, pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved;
- our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications;
- our ongoing and planned clinical trials;
- our ability to expand the scope of our license agreement with Bioprojet Société Civile de Recherche ("Bioprojet");
- the availability of favorable insurance coverage and reimbursement for WAKIX;
- the impact of the COVID-19 pandemic;
- the timing of, and our ability to obtain, regulatory approvals for pitolisant for other indications as well as any other product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;
- our commercialization, marketing and manufacturing capabilities and strategy;
- significant competition in our industry;
- our intellectual property position;
- loss or retirement of key members of management;
- failure to successfully execute our growth strategy, including any delays in our planned future growth;
- our failure to maintain effective internal controls; and
- the impact of government laws and regulations.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential", or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of

important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the 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.

Company Overview

We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action (“MOA”) specifically designed to increase histamine signaling in the brain by binding to H₃ receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of excessive daytime sleepiness (“EDS”) in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. On October 13, 2020, WAKIX was approved by the FDA for the treatment of cataplexy in adult patients with narcolepsy. WAKIX is the first-and-only approved product for patients with narcolepsy that is not scheduled as a controlled substance by the Drug Enforcement Administration (the “DEA”).

We plan to pursue label expansion for WAKIX in narcolepsy in pediatric patients and engage with the FDA in pursuit of pediatric exclusivity. Our strategic partner, Bioprojet is evaluating pitolisant in pediatric patients with narcolepsy in a Phase 3 trial. Bioprojet amended the protocol and increased the number of patients in the trial which has pushed out the timeline for trial completion and read out of the data. We and Bioprojet have decided to wait for the read out of the data to inform how best to advance the pediatric narcolepsy program. We believe that our strategic decision to wait for this data before advancing the pediatric program is the most prudent and thoughtful path forward from a development and financial perspective. In the meantime, we are continuing to evaluate regulatory strategies with regard to obtaining pediatric exclusivity. We anticipate providing an update on the path forward in the coming months.

We believe that pitolisant’s ability to regulate histamine gives it the potential to provide therapeutic benefit in other rare neurological disorders that are mediated through H₃ receptors and histamine signaling. Beyond narcolepsy, we are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome (“PWS”) and myotonic dystrophy, otherwise known as dystrophia myotonica (“DM”). In December 2020, we initiated a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS and other key symptoms in patients with PWS and anticipate topline results from this trial in the first half of 2022. We are also planning to commence a Phase 2 clinical trial in adult patients with DM1 in the first half of 2021, with topline results expected in the second half of 2022. Beyond these indications, we intend to further explore pitolisant in other

rare neurological disorders in which fatigue and cognitive impairment are prominent symptoms with significant impact on daily functioning.

We also seek to expand our pipeline through the acquisition of additional assets that focus on addressing the unmet needs of patients with neurological disorders. We intend to target assets that will be complementary to WAKIX and our expanding list of potential new indications for WAKIX, and/or assets that will allow us to further leverage the expertise and infrastructure that we have successfully built at Harmony.

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

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

Liquidity and Sources of Funding

For the three months ended March 31, 2021, we generated \$59.7 million of net product revenues. We have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock, (b) borrowings under (i) our multi-draw term loan agreement (the “Loan Agreement”) with CRG Servicing LLC (“CRG”) and (ii) our credit agreement (the “Credit Agreement”) with OrbiMed Royalty & Credit Opportunities III, LP (“OrbiMed”), and (c) proceeds from our initial public offering (“IPO”) in August 2020. As of March 31, 2021, we had cash, cash equivalents and restricted cash of \$141.9 million and accumulated deficit of \$480.8 million. As of March 31, 2021, we had outstanding debt, net of issuance costs, of \$194.9 million.

We believe that our anticipated cash from operating and financing activities and existing cash and cash equivalents will enable us to meet our operational liquidity needs and fund planned investing activities for the next twelve months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect. See “—Liquidity and Capital Resources.”

Our revenues and expenses in future quarters may differ from our expectations as we:

- commercialize WAKIX in the United States for the treatment of EDS or cataplexy in adult patients with narcolepsy;
- incur sales and marketing costs to support the commercialization of WAKIX and any additional product candidates;
- pay royalties and make milestone payments to Bioprojet for the license of WAKIX;
- incur manufacturing costs for WAKIX and any additional product candidates;
- implement post-approval requirements related to WAKIX;
- conduct clinical trials in PWS, DM, and potential new indications for pitolisant or any additional product candidates;
- conduct a pediatric narcolepsy program in pursuit of an indication and extension of our patents based on pediatric exclusivity;

- conduct earlier stage research and development activities for pitolisant;
- support independent investigator-initiated research for which there is a valid scientific rationale;
- hire additional personnel;
- invest in measures to protect and expand our intellectual property;
- incur interest expenses in conjunction with our debt facility;
- seek regulatory approvals for pitolisant or any additional product candidates that successfully complete clinical development;
- conduct additional clinical trials in pursuit of potential new indications for pitolisant; acquire or in-license other assets and technologies; and
- incur additional costs associated with being a public company.

Commercial Launch Metrics

As of March 31, 2021, over 2,700 unique healthcare professionals (“HCPs”) (out of a total of approximately 8,000 HCPs who treat approximately 90% of diagnosed narcolepsy patients) have prescribed WAKIX since it became available in November 2019. The average number of patients on WAKIX at March 31, 2021 was approximately 2,800. Additionally, as of March 31, 2021, we have secured formulary access for approximately 80% of all insured lives (Commercial, Medicare and Medicaid) in the United States. Within these covered lives, we have observed favorable access to WAKIX subsequent to the expanded approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020.

COVID-19 Business Update

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

Despite our response strategy, the COVID-19 pandemic is having an effect on our business and the pharmaceutical industry in general, and is impacting the way stakeholders interact with one another during this pandemic. We continue to leverage technology and virtual engagement initiatives to offset our reduced in-person access to HCPs. The COVID-19 pandemic, which has led to high unemployment and corresponding loss of medical insurance, has caused a change in relationship dynamics between patients and their HCPs and has impacted the way patients take, or do not take, their medication. Based on these factors, we expect that the revenue growth rate in future quarters may be adversely impacted by the ongoing COVID-19 pandemic.

We continue to identify new and innovative ways to maintain meaningful engagement, generate awareness and educate our patients, HCPs and payors to minimize the pressure from the COVID-19 pandemic on our business and support our commercial launch performance.

Commercialization

With respect to our commercialization activities, we believe the COVID-19 pandemic is putting pressure on top-line prescription demand for WAKIX, primarily due to (i) our field sales team’s reduced ability to access HCPs in person, and (ii) fewer patients seeing HCPs for prescriptions or treatments. The impact on demand for WAKIX may also be related to a reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, the reduced ability to see patients due to (i) cancelled appointments and (ii) the reprioritization of healthcare resources toward the treatment of COVID-19, both of which lead to fewer prescriptions. Despite these challenges, we continue to engage and educate HCPs virtually on the overall benefit/risk profile of WAKIX and continue to provide support for people living with narcolepsy. As offices, clinics and institutions have begun to allow limited in-person interactions pursuant to health authority and local government guidelines, our field teams continue to re-initiate in-person interactions with HCPs and customers, but the timing and level of engagement vary by account and region and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19 may occur.

High unemployment and the corresponding loss of health insurance is causing some eligible patients to shift from commercial insurance to free goods and patient assistance programs, which impacts our ability to convert demand to revenue. Depending on the scale and ultimate duration of the COVID-19 pandemic and the extent of an economic slowdown, widespread unemployment and resulting loss of employer-sponsored insurance coverage, we may experience a shift from commercial payor coverage to government payor coverage or continued/increased demand for patient assistance and/or free drug programs, which could further impact our net revenue in the coming quarters.

Supply Chain

We currently expect to have adequate supply of WAKIX through the third quarter of 2022, with additional API on-hand inventory to support 18 to 24 months beyond this time frame. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the COVID-19 pandemic. We believe that our access to the required production lines to produce additional API and WAKIX finished product throughout the next 12-18 months will not be directly impacted by the potential need to reprioritize manufacturing resources due to the production of materials utilized for COVID-19 vaccines.

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

Research and Development

The COVID-19 pandemic has negatively impacted the pharmaceutical industry's ability to conduct clinical trials. While we initially experienced some challenges due to the COVID-19 pandemic, we have taken measures and put contingency plans in place in order to advance our clinical development programs. We have implemented remote and virtual approaches to clinical trials, including using telemedicine for remote clinic visits to perform efficacy assessments and sending out licensed HCPs to each patient to collect safety assessments (e.g. labs, electrocardiograms) as required by the protocols. We are also performing remote site visits and data monitoring where possible. These measures are being instituted with the intent of maintaining patient safety and trial continuity while preserving study integrity. One unique challenge we are facing is the ability to access sleep labs during the COVID-19 pandemic in order to conduct objective sleep testing, which is required for some of our clinical trials. In addition, we rely on contract research organizations ("CROs") or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time, or reemerges in the future, we could experience significant delays in our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Corporate Development and Other Financial Impacts

The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of domestic and global financial markets. If the disruption persists and/or worsens, we may be unable to access additional capital, which could negatively affect our ability to execute on certain corporate development transactions or other important investment opportunities. The pandemic could also impact our ability to conduct in-person due diligence, negotiations, and other interactions to identify new opportunities.

The COVID-19 pandemic has also affected, and continues to affect, our business operations and financial results. The extent of the impact of the COVID-19 pandemic on our ability to generate sales of, and revenues from, our approved products, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of or reemergence of outbreaks, governmental travel restrictions, quarantines, social distancing and business closure requirements in the United States, France, and other countries, and the effectiveness of actions taken globally to contain and treat COVID-19.

Corporate Responsibility Impact

We continue to provide support to our local communities, patient-focused organizations and other charitable organizations during the COVID-19 pandemic with relief efforts, including corporate donations, supplying food, medical supplies and other resources. For the safety and well-being of our employees, consultants and their families, during the COVID-19 pandemic, we have abided by government-issued work from home orders. We continue to clean and sanitize our offices on a regular basis and have implemented COVID-19 screening procedures and social distancing guidelines before allowing employees or guests to enter our offices.

Financial Operations Overview

Revenue

We did not generate any revenue from inception until the fourth quarter of 2019. Our current product, WAKIX, was approved by the FDA for the treatment of EDS in adult patients with narcolepsy in August 2019, became commercially available in November 2019 and was approved by the FDA for the treatment of cataplexy in adult patients with narcolepsy in October 2020. For the three months ended March 31, 2021 and 2020, we had \$59.7 million and \$19.8 million, respectively, of net product revenue. The increase was due to the growing commercial sales of WAKIX which was launched on November 1, 2019 and the price increase of WAKIX in connection with the cataplexy indication approval in the fourth quarter of 2020.

Total revenue consists of net sales of WAKIX. Net sales represent the gross sales of WAKIX less provisions for product sales discounts and allowances. At this time, these provisions include trade allowances, rebates to government and commercial entities, and discounts. Although we expect net sales to increase over time, the provisions for product sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in our accrual estimates.

Cost of Product Sales

Cost of product sales includes manufacturing and distribution costs, the cost of the drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs and salaries of employees involved with production. We began capitalizing inventory upon FDA approval of WAKIX. Excluded from cost of product sold is amortization of acquired developed technology of \$4.6 million and \$1.8 million in the three months ended March 31, 2021 and 2020, respectively.

Previously expensed inventory that was manufactured in anticipation for commercialization preapproval has not had a material impact on our historical results of operations and is not expected to have a material impact on future results of operations. Further, previously expensed inventory has not had a material impact on our gross margin percentage historically, and we do not anticipate a material impact on our gross margin percentage once our previously expensed inventories have been exhausted. Our cost of product sales is increasing moderately as we continue to ramp up production and sales infrastructure to meet expected demand for WAKIX.

The shelf life of our product is three years from date of manufacture, with the earliest expiration of current inventory expected to be May 2022. We regularly review our inventory for obsolescence and expect write-offs from time to time. We will continue to assess obsolescence in future periods as demand for WAKIX and the rate of inventory turnover evolves.

Research and Development Expenses

Our research and development expenses have been applied toward the license of the rights to pitolisant, the conduct of an Expanded Access Program (“EAP”) to provide appropriate patients with pitolisant at no cost as part of a clinical trial to assess safety prior to the approval of WAKIX, the preparation of the NDA, and the initiation of development programs for potential new indications for pitolisant in patients with PWS and DM. We also have research and development expenses related to our team of Medical Science Liaisons (“MSLs”) who interact with key opinion leaders, with a focus on the science, the role of histamine in sleep-wake state stability and the novel mechanism of action of pitolisant. In addition, our MSLs support our market access team with clinical data presentations to payors upon request. Research and development costs are expensed as incurred. We have significantly increased our research and development efforts as we advance our clinical programs in PWS and DM, and assess other product candidates to expand our pipeline. Research and development expenses include:

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

Currently, WAKIX is our only product and we do not currently track our internal research and development expenses on an indication-by-indication basis. A significant portion of our research and development costs are external costs, such as fees paid to CROs and CMOs, central laboratories, contractors, and consultants in connection with our clinical development activities. Internal expenses primarily relate to personnel, early research and consumable costs, which are deployed across multiple programs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, milestone payments, and the cost of submitting an NDA to the FDA (and/or other regulatory authorities). We expect our research and development expenses to be significant over the next several years as we advance our current clinical development programs and prepare to seek regulatory approval for additional indications for pitolisant as well as potential new product candidates.

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 for clinical trials of our current development programs and any further clinical trials related to new product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- the impact of the COVID-19 pandemic on the ability to initiate new clinical trials and/or maintain the continuity of ongoing clinical trials that could be impacted by future shelter-in-place orders and needs of the health care system to focus on managing patients affected by COVID-19;
- receiving Bioprojet’s consent to pursue additional indications for pitolisant;
- the acceptance of INDs for our planned clinical trials or future clinical trials;
- the successful and timely enrollment and completion of clinical trials;
- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- the entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; and

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

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

Sales and Marketing Expenses

Our sales and marketing expenses have primarily been limited to the market development and launch activities of WAKIX for the treatment of EDS or cataplexy in adult patients with narcolepsy. Market development and commercial launch activities account for a significant portion of the overall company operating expenses and are expensed as they are incurred. Our sales and marketing expenses are increasing in the near- and mid-term to support our indications for the treatment of EDS or cataplexy in adult patients with narcolepsy and to expand our portfolio with the anticipated growth from potential additional indications.

Sales and marketing expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our sales and marketing personnel;
- healthcare professional-related expenses, including marketing programs, healthcare professional promotional medical education, disease education, conference exhibits and market research;
- patient-related expenses, including patient awareness and education programs, disease awareness education, patient reimbursement programs, patient support services and market research;
- market access expenses, including payor education, specialty pharmacy programs and services to support the continued commercialization of WAKIX; and
- secondary data purchases (i.e. patient claims and prescription data), data warehouse development and data management.

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

General and Administrative Expenses

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

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

Paragon Agreements

We were party to a management services agreement (the "Management Services Agreement") with Paragon Biosciences, LLC ("Paragon"), effective on September 22, 2017 through the consummation of our IPO, pursuant to which Paragon provided us with certain professional services. In exchange for services provided to us under the Management Services Agreement, we paid Paragon a management fee of \$0.3 million per each calendar month.

We are also party to a right-of-use agreement with Paragon whereby we have access to and the right to use certain office space leased by Paragon in Chicago, Illinois. For the three months ended March 31, 2021, we paid de minimis fees pursuant to this agreement.

Loss on Debt Extinguishment

Loss on debt extinguishment consists primarily of costs of extinguishment of debt during the period related to the prepayment of the Loan Agreement with CRG.

Other Income / Expense, Net

Other income / expense, net consists primarily of costs of the fair value of the warrants associated with the Credit Agreement we entered into with OrbiMed.

Interest Income / Interest Expense

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

Results of Operations

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

	For the Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Net product revenue	\$ 59,674	\$ 19,840
Cost of product sales	10,409	3,474
Gross profit	49,265	16,366
Operating expenses:		
Research and development	4,679	3,431
Sales and marketing	15,506	13,254
General and administrative	14,547	9,290
Total operating expenses	34,732	25,975
Operating income (loss)	14,533	(9,609)
Loss on debt extinguishment	—	(22,639)
Other expense, net	(20)	—
Interest expense, net	(7,127)	(6,372)
Net income (loss) before provision for income taxes	7,386	(38,620)
Provision for income taxes	—	—
Net income (loss)	\$ 7,386	\$ (38,620)

Net Product Revenue

Net product revenue increased by \$39.8 million, or 200.8%, for the three months ended March 31, 2021 compared to the same period in 2020. The increase was due to the growing commercial sales of WAKIX which was launched on November 1, 2019 and the price increase of WAKIX in connection with the cataplexy indication approval in the fourth quarter of 2020.

Cost of Product Sales

Cost of product sales increased by \$6.9 million, or 199.6%, for the three months ended March 31, 2021 compared to the same period in 2020. The increase was due to the growing commercial sales of WAKIX, which was launched on November 1, 2019. Cost of product sales is primarily comprised of the royalty payment to Bioprojet.

Research and Development Expenses

Research and development expenses increased by \$1.2 million, or 36.4%, for the three months ended March 31, 2021 as compared to the same period in 2020. The increase was primarily due to clinical development work associated with PWS and DM.

Sales and Marketing Expenses

Sales and marketing expenses increased by \$2.3 million, or 17.0%, for the three months ended March 31, 2021 as compared to the same period in 2020. The increase was primarily due to patient engagement and marketing activities.

General and Administrative Expenses

General and administrative expenses increased by \$5.3 million, or 56.6%, for the three months ended March 31, 2021 as compared to the same period in 2020. This is primarily due to intangible asset amortization of the milestone payment made in connection with the FDA's approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020, stock compensation associated with new awards, and the additional cost of public company insurance, offset by fees paid to Paragon.

Loss on Debt Extinguishment

Loss on debt extinguishment decreased \$22.6 million, or 100%, for the three months ended March 31, 2021 as compared to the same period in 2020 due to costs of extinguishment of debt during the period related to the prepayment of the Loan Agreement with CRG.

Other Expense, Net

Other expense remained relatively flat for the three months ended March 31, 2021, as compared to the same period in 2020.

Interest Expense, Net

Interest expense increased by \$0.8 million, or 11.8%, for the three months ended March 31, 2021, as compared to the same period in 2020 primarily due to payment of interest on the Loan Agreement and amortization of debt issuance costs compared to the payment of interest on the Credit Agreement and amortization of debt issuance costs.

Income Taxes

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

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock, (b) borrowings under (i) our Loan Agreement with CRG and (ii) our Credit Agreement with OrbiMed, and (c) the proceeds from our IPO. From our inception through March 31, 2021, we have received aggregate proceeds of \$345.0 million from sales of our convertible preferred stock. On August 21, 2020, we completed the IPO of our common stock, in which we sold 6,151,162 shares of our common stock, including 802,325 shares of our common stock pursuant to the underwriters' over-allotment option. The shares began trading on the Nasdaq Global Market on August 19, 2020. The shares were sold at a price of \$24.00 per share for net proceeds of approximately \$135.4 million. As of March 31, 2021, we had cash, cash equivalents and

restricted cash of \$141.9 million and accumulated deficit of \$480.8 million. As of March 31, 2021, we had outstanding debt, net of issuance costs, of \$194.9 million.

The 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 have incurred operating losses and negative cash flows from operations since inception resulting in an accumulated deficit of \$480.8 million as of March 31, 2021.

We believe that our anticipated cash from operating and financing activities and existing cash and cash equivalents will enable us to meet our operational liquidity needs and fund our planned investing activities for the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect. See “—Overview—Liquidity and Sources of Funding.”

OrbiMed Credit Agreement

On February 28, 2019, we entered into the Loan Agreement with CRG for an aggregate of \$200.0 million of which \$102.5 million was outstanding as of December 31, 2019. On January 9, 2020, we entered into the Credit Agreement with OrbiMed for an aggregate of \$200.0 million and paid off all of our obligations under the Loan Agreement. Borrowings under the Credit Agreement are collateralized by all of the Company’s assets, excluding the intellectual property licensed through the Bioprojet License Agreement. At the time of prepayment or repayment of all or any portion of the principal of the OrbiMed Loan, the Company is required to pay an exit fee of 7.0% of the principal amount of the OrbiMed Loan prepaid, repaid, or required to be prepaid or repaid. The Credit Agreement matures on January 9, 2026 and bears an interest rate of the greater of (a) LIBOR or (b) 2.00% per annum, plus 11.00% per annum. When the LIBOR rate is no longer used post-2021, the Prime Rate will be used in the determination of the interest rate. The Credit Agreement requires compliance with certain financial covenants, including minimum net revenue thresholds and cash balance requirements (which include maintaining minimum liquidity of \$12.5 million), and financial reporting requirements. We have been in compliance with the financial covenants under the Credit Agreement since it was entered into on January 9, 2020. The Credit Agreement also contains certain negative restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event we, engage in new lines of business, incur additional indebtedness or liens, make certain investments, make certain payments, pay cash dividends, merge with other companies or consummate certain changes of control, acquire other companies, transfer or dispose of certain assets, liquidate or dissolve, amend certain material agreements, enter into sale and leaseback transactions, enter into various other specified transactions, and change our name, location, executive office or executive management without notice.

Recent Milestone Payment

Upon FDA approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020 (the “Cataplexy Milestone Trigger Date”), we became obligated to make the \$100.0 million milestone payment (the “Cataplexy Milestone Payment”) to Bioprojet pursuant to the terms of the Bioprojet License Agreement. Subsequently, in October 2020, we made a payment to Bioprojet of \$2.0 million to extend the Cataplexy Milestone Payment due date to within 90 days of the Cataplexy Milestone Trigger Date. On January 6, 2021, we made the \$100.0 million Cataplexy Milestone Payment in full to Bioprojet.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ 12,530	\$ (26,702)
Investing activities	(100,004)	-
Financing activities	12	73,762

Operating Activities

Net cash provided by operating activities increased to \$12.5 million for the three months ended March 31, 2021 as compared to net cash used in operation activities of \$26.7 million for the same period in 2020. This decrease was primarily attributable to company revenue growth and net income associated with the commercialization of WAKIX.

Net cash provided by operating activities for the three months ended March 31, 2021 consisted of our net income of \$7.4 million adjusted for non-cash items of \$3.3 million related to stock compensation expense and \$4.6 million related to intangible amortization and fair value of warrants.

Net cash used in operating activities for the three months ended March 31, 2020 consisted of our net loss of \$38.6 million adjusted for non-cash items of \$22.6 million associated with loss on extinguishment of debt and \$3.0 million related to intangible amortization and fair value of warrants. Net working capital excluding cash decreased by \$14.6 million due to company growth and the commercial launch of WAKIX.

Investing Activities

Net cash used in investing activities increased to \$100.0 million for the three months ended March 31, 2021 as compared to \$0.0 million for the same period in 2020. This change was primarily attributable to the \$100.0 million milestone payment associated with the Bioprojet License Agreement.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 was \$0.0 million, as compared to \$73.7 million for the same period in 2020. This change was primarily attributable to \$194.2 million associated with the OrbiMed Credit Agreement net of issuance, offset with \$120.9 million of repayment and exit fees associated with the CRG Loan Agreement.

Off-Balance Sheet Arrangements

For the three months ended March 31, 2021 and 2020, we did not have any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis.

Significant estimates include assumptions used in the determination of some of our costs incurred under our services type agreements and which costs are charged to research and development and general and administrative expense. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Recent Accounting Pronouncements

See Note 3 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information.

The JOBS Act

We are an “emerging growth company”, or EGC, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. If we were to subsequently elect instead to comply with these public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We will remain an EGC until the earliest of (i) the last day of our fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our common stock, (b) in which we have total annual gross revenues of at least \$1.07 billion or (ii) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities over a three-year period.

Non-GAAP Financial Measures

In addition to our GAAP results, we provide certain non-GAAP metrics including adjusted net income and adjusted net income per share. We believe that the presentation of these measures provides important supplemental information to management and investors regarding our performance. These measurements are not a substitute for GAAP measurements, and the manner in which we calculate adjusted net income and adjusted net income per share may not be identical to the manner in which other companies calculate adjusted net income and adjusted net income per share. Management uses these non-GAAP measurements as an aid in monitoring our on-going financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies.

EBITDA is intended to provide a measure of the Company’s operating performance as it eliminates the effects of financing and capital expenditures. EBITDA consists of GAAP net loss excluding: (i) interest expense, (ii) income tax provision, (iii) depreciation and (iv) amortization of intangibles.

Non-GAAP adjusted net income (loss) and non-GAAP adjusted net income (loss) per share are intended to provide an enduring, normalized view of net income and our broader business operations that we expect to experience on an ongoing basis by removing items which may be irregular, one-time, or non-recurring from net income. This enables us to identify underlying trends in our business that could otherwise be masked by such items.

Non-GAAP adjusted net income (loss) consists of GAAP net loss excluding: (i) interest expense, (ii) income tax provision, (iii) depreciation, (iv) amortization of intangibles, (v) stock-based compensation, (vi) loss on debt extinguishment, and (vii) warrant expense.

A reconciliation of GAAP net loss to non-GAAP adjusted net income (loss) appears in the table below (in thousands except share and per share data):

	For the Three Months Ended March 31,	
	2021	2020
Net income (loss)	\$ 7,386	\$ (38,620)
Non-GAAP Adjustments:		
Interest expense	7,127	6,372
Taxes	—	—
Depreciation	100	97
Amortization	4,579	1,786
EBITDA	19,192	(30,365)
Additional Non-GAAP Adjustments:		
Stock-based compensation expense	3,251	368
Loss on debt extinguishment	—	22,639
Warrant expense	—	1,146
Non-GAAP adjusted net income (loss)	\$ 22,443	\$ (6,212)
Accumulation of yield on preferred stock	—	(10,445)
Non-GAAP adjusted net income (loss) available to common stockholders	22,443	(16,657)
GAAP reported net income (loss) per diluted share	\$ 0.13	\$ (6.30)
Non-GAAP adjusted net income (loss) per diluted share	0.38	(2.14)
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,805,285	7,790,667

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2021, our cash and cash equivalents consisted of cash and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of March 31, 2021, we had \$200.0 million in borrowings outstanding. The term loan bears interest at an interest rate of the greater of (a) LIBOR or (b) 2.00% per annum, plus 11.00% per annum. Based on the \$200.0 million of principal outstanding as of March 31, 2021, an immediate 10% change in the Prime Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

Foreign Currency Fluctuation Risk

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

Inflation Fluctuation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations for the three months ended March 31, 2021 or 2020.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2021. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

“Item 1A. Risk Factors” of our Form 10-K includes a discussion of our known material risk factors, other than risks that could apply to any issuer or offering. There have been no material changes from the risk factors described in our Form 10-K.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed
		Form	Date	Number	Herewith
3.1	Amended and Restated Certificate of Incorporation of Harmony Biosciences Holdings, Inc.	8-K	August 21, 2020	3.1	
3.2	Amended and Restated Bylaws.	8-K	August 21, 2020	3.2	
10.1+	Confidential Separation Agreement and General Release, between Harmony Biosciences, LLC and Susan L. Drexler, dated March 4, 2021.	8-K	March 10, 2021	10.1	
10.2+	Employment Agreement, dated March 4, 2021, between Harmony Biosciences, LLC and Sandip Kapadia.	8-K	March 15, 2021	10.1	
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.				X
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.				X
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.				X
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.				X
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2021 formatted in Inline XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) and (vi) Notes to Financial Statements, tagged as blocks of text and including detailed tags.				X

* 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,

[Table of Contents](#)

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.

+ Indicates management contract or compensatory plan.

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

By: /s/ John C. Jacobs
Name: John C. Jacobs
Title: President, Chief Executive Officer and Director (principal executive officer)
Date: May 11, 2021

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer (principal financial officer)
Date: May 11, 2021

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John C. Jacobs, certify that:

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

Date: May 11, 2021	By:	/s/ John C. Jacobs
		John C. Jacobs
		Chief Executive Officer, President and Director (Principal Executive Officer)

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sandip Kapadia, certify that:

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

Date: May 11, 2021

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

Date: May 11, 2021	By:	/s/ John C. Jacobs
		John C. Jacobs
		Chief Executive Officer, President and Director (Principal Executive Officer)

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

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

Date: May 11, 2021	By:	/s/ Sandip Kapadia
		Sandip Kapadia
		Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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

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