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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 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	**82-2279923**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
630 W. Germantown Pike, Suite 215, Plymouth Meeting, PA	**19462**
(Address of principal executive offices)	(Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 value per share	HRMY	The Nasdaq Stock Market LLC (Nasdaq Global Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of November 5, 2021, there were 58,471,519 shares of the registrant's common stock, par value $0.00001 value per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 189,704	$ 228,631
Trade receivables, net	33,206	22,176
Inventory, net	4,805	3,823
Prepaid expenses	9,793	6,959
Other current assets	3,183	1,302
Total current assets	240,691	262,891
NONCURRENT ASSETS:		
Property and equipment, net	937	938
Restricted cash	750	750
Intangible assets, net	148,562	162,343
Other noncurrent assets	152	152
Total noncurrent assets	150,401	164,183
TOTAL ASSETS	$ 391,092	$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 4,179	$ 2,556
Accrued compensation	6,785	8,942
Accrued expenses	34,223	122,727
Current portion of long term debt	2,000	—
Other current liabilities	436	314
Total current liabilities	47,623	134,539
NONCURRENT LIABILITIES:		
Long term debt, net	190,069	194,250
Other noncurrent liabilities	1,382	1,105
Total noncurrent liabilities	191,451	195,355
TOTAL LIABILITIES	239,074	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.00001 par value; 10,000,000 shares and 00 shares authorized at September 30, 2021 and December 31, 2020, respectively; 00 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 58,414,546 shares and 56,890,569 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	628,329	585,374
Accumulated deficit	(476,312)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	152,018	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 391,092	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net product revenues	$ 80,732	$ 45,609	$ 214,227	$ 103,454
Cost of product sold	14,604	7,890	37,701	17,820
Gross profit	66,128	37,719	176,526	85,634
Operating expenses:				
Research and development	11,739	4,230	22,916	11,829
Sales and marketing	16,480	12,601	49,009	38,297
General and administrative	16,856	10,508	45,704	26,280
Total operating expenses	45,075	27,339	117,629	76,406
Operating income	21,053	10,380	58,897	9,228
Loss on debt extinguishment	(26,146)	—	(26,146)	(22,639)
Other income (expense), net	—	(1,525)	(15)	(3,071)
Interest expense, net	(5,429)	(6,946)	(19,783)	(20,254)
(Loss) income before income taxes	(10,522)	1,909	12,953	(36,736)
Income tax benefit (expense)	902	—	(1,070)	—
Net (loss) income and comprehensive (loss) income	$ (9,620)	$ 1,909	$ 11,883	$ (36,736)
Accumulation of dividends on preferred stock	—	(6,013)	—	(26,904)
Net (loss) income available to common stockholders	$ (9,620)	$ (4,104)	$ 11,883	$ (63,640)
(LOSS) EARNINGS PER SHARE:				
Basic	$ (0.17)	$ (0.14)	$ 0.21	$ (4.15)
Diluted	$ (0.17)	$ (0.14)	$ 0.20	$ (4.15)
Weighted average number of shares of common stock - basic	57,722,163	30,212,959	57,188,101	15,324,362
Weighted average number of shares of common stock - diluted	57,722,163	30,212,959	58,776,158	15,324,362

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	—	—	—	11,883	11,883
Issuance of common stock	1,270,462	—	29,700	—	29,700
Exercise of stock options	253,515	—	1,794	—	1,794
Stock-based compensation	—	—	11,461	—	11,461
Balance as of September 30, 2021	58,414,546	$ 1	$ 628,329	$ (476,312)	$ 152,018

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount			
Balance as of June 30, 2021	57,000,139	$ 1	$ 593,242	$ (466,692)	$ 126,551
Net income	—	—	—	(9,620)	(9,620)
Issuance of common stock	1,270,462	—	29,700	—	29,700
Exercise of options	143,945	—	1,134	—	1,134
Stock-based compensation	—	—	4,253	—	4,253
Balance as of September 30, 2021	58,414,546	$ 1	$ 628,329	$ (476,312)	$ 152,018

	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	—	—	—	—	—	(36,736)	(36,736)
Preferred stock dividend, Series A	—	22,780	—	—	(1,048)	(21,732)	(22,780)
Preferred stock accretion, Series A	—	5,562	—	—	(3,572)	(1,990)	(5,562)
Preferred stock dividend, Series B	—	777	—	—	1	(778)	(777)
Preferred stock accretion, Series B	—	53	—	—	(37)	(16)	(53)
Preferred stock dividend, Series C	—	3,347	—	—	—	(3,347)	(3,347)
Preferred stock accretion, Series C	—	921	—	—	(563)	(359)	(922)
Issuance of stock upon initial public offering, net of issuance costs	—	—	6,151,162	—	135,435	—	135,435
Issuance of Series A, B, C convertible stock to common stock	(318,510,205)	(444,715)	42,926,630	1	444,715	—	444,716
Reclassification of warrant liability to equity	—	—		—	5,468	—	5,468
Exercise of stock options	—	—	36,003	—	283	—	283
Stock-based compensation	—	—	—	—	1,870	—	1,870
Repurchase and cancellation of common units	—	—	(12,175)	—	—	(167)	(167)
Repurchase and cancellation of common units withheld for taxes	—	—	(465)	—	(17)	—	(17)
Balance as of September 30, 2020	—	$ —	56,888,625	$ 1	$ 582,535	$ (487,987)	$ 94,549

	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 June 30, 2020	318,510,205	$ 434,009	7,805,848	$ —	$ —	$ (483,362)	$ (483,362)
Net loss	—	—	—	—	—	1,909	1,909
Preferred stock dividend, Series A	—	5,091	—	—	—	(5,091)	(5,091)
Preferred stock accretion, Series A	—	4,010	—	—	(3,572)	(438)	(4,010)
Preferred stock dividend, Series B	—	174	—	—	—	(174)	(174)
Preferred stock accretion, Series B	—	41	—	—	(37)	(4)	(41)
Preferred stock dividend, Series C	—	748	—	—	—	(748)	(748)
Preferred stock accretion, Series C	—	642	—	—	(563)	(79)	(642)
Issuance of stock upon initial public offering, net of issuance costs	—	—	6,151,162	—	135,435	—	135,435
Issuance of Series A, B, C convertible stock to common stock	(318,510,205)	(444,715)	42,926,630	1	444,715	—	444,716
Reclassification of warrant liability to equity	—	—	—	—	5,468	—	5,468
Exercise of options	—	—	5,450	—	33	—	33
Stock-based compensation	—	—	—	—	1,073	—	1,073
Repurchase and cancellation of common units withheld for taxes	—	—	(465)	—	(17)	—	(17)
Balance as of September 30, 2020	—	$ —	56,888,625	$ 1.00	$ 582,535	$ (487,987)	$ 94,549

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)

	Nine Months Ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 11,883	$ (36,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	299	294
Intangible amortization	13,781	5,560
Stock-based and employee stock purchase compensation expense	11,461	1,870
Stock appreciation rights market adjustment	261	396
Warrant expense	—	3,109
Debt issuance costs amortization	1,820	1,020
Loss on debt extinguishment	26,146	22,639
Change in operating assets and liabilities:		
Trade receivables	(11,030)	(12,071)
Inventory	(982)	(1,223)
Prepaid expenses and other assets	(3,715)	(8,169)
Other non-current assets	—	(476)
Trade payables	1,623	2,987
Accrued expenses and other current liabilities	9,461	7,738
Other non-current liabilities	16	30
Net cash provided by (used in) operating activities	61,024	(13,032)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(298)	(2)
Milestone payments	(100,000)	—
Net cash used in investing activities	(100,298)	(2)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon initial public offering	—	147,628
Initial public offering issuance costs	—	(11,021)
Proceeds from issuance of common stock	30,000	—
Common stock issuance costs	(300)	—
Proceeds from long term debt	200,000	200,000
Debt issuance costs	(9,147)	(5,804)
Extinguishment of debt	(200,000)	(102,538)
Extinguishment of debt exit fees	(22,000)	(18,047)
Proceeds from exercised options	1,794	283
Repurchase of common stock	—	(167)
Tax payments for employees shares withheld	—	(17)
Net cash provided by financing activities	347	210,317
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(38,927)	197,283
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	229,381	25,207
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 190,454	$ 222,490
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 15,997	$ 19,549
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Series A Preferred Stock accrued return	—	22,780
Series A accretion of issuance costs	—	5,562
Series B Preferred Stock accrued return	—	777
Series B accretion of issuance costs	—	53
Series C Preferred Stock accrued return	—	3,347
Series C accretion of issuance costs	—	921
Warrant financing	—	2,359
Warrant liability reclassified to equity	—	5,468

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, rare disease 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 unaudited 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 $476,312 and $488,195, as of September 30, 2021 and December 31, 2020, respectively. As of September 30, 2021, the Company had cash and cash equivalents of $189,704.

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). On January 9, 2020, the Company received aggregate proceeds of approximately $200,000 through the loan agreement with OrbiMed Royalty & Credit Opportunities, LP ("OrbiMed"). 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.

On August 9, 2021, the Company sold 1,048,951 shares of the Company's common stock to Blackstone Alternative Credit Advisors ("Blackstone") at a price per share of $28.60 for gross proceeds of $30,000. In addition, the Company received aggregate proceeds of approximately $200,000 through the credit agreement ("Blackstone Credit Agreement") with Blackstone and repaid in full the loan with OrbiMed (see note 8).

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 unaudited condensed consolidated balance sheet as of September 30, 2021, the unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020, and the unaudited condensed consolidated statements of operations and comprehensive income (loss) and the unaudited condensed consolidated statements of convertible preferred stock and shareholders' equity (deficit) for the three and nine months ended September 30, 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 presentation of the Company's financial position as of September 30, 2021, and the results of its operations and its cash flows for the three and nine months ended September 30, 2021 and 2020. The unaudited condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and note disclosures of the Company normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 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 unaudited condensed consolidated financial statements, including the notes thereto, and elsewhere in this report. Uncertainties related to the magnitude and duration of COVID-19, the extent to which it will impact our estimated future financial results, worldwide macroeconomic conditions including interest rates, employment rates, consumer spending and health insurance coverage, the speed of the anticipated recovery and governmental and business reactions to the pandemic have increased the complexity of developing these estimates, including the carrying amounts of long-lived assets, and the intangible asset. Actual results may differ significantly from our estimates, including as a result of COVID-19.

Fair Value of Financial Instruments

The Company's unaudited condensed consolidated financial statements include cash, cash equivalents, restricted cash, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value. Additionally, prior to the IPO, the Company's unaudited 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 and restricted cash consist of cash and, if applicable, highly liquid investments with an original maturity of three months or less when purchased, including investments in Money Market Funds. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that equal the amount reflected in the statements of cash flows.

	As of	
	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 189,704	$ 228,631
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 190,454	$ 229,381

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 September 30, 2021, three customers accounted for 100% of gross accounts receivable; Caremark LLC ("CVS Caremark"), which accounted for 36% of gross accounts receivable; PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 34% 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 nine months ended September 30, 2021, three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 36% of gross product revenues; Pantherx accounted for 36% of gross product revenues; and Accredo accounted for 28% of gross product revenues. For the nine months ended September 30, 2020 three customers accounted for 100% of gross product revenues; CVS Caremark accounted for 40% of gross product revenues; Pantherx accounted for 34% of gross product revenues; and Accredo accounted for 26% of gross product revenues.

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

Agreement Related to Intellectual Property

In August 2021, The Company entered into an asset purchase agreement with ConSynance Therapeutics, Inc. to acquire HBS-102 (formerly referred to as "CSTI-100"), a potential first-in-class molecule with a novel mechanism of action. Under the terms of the agreement, the Company acquired full development and commercialization rights globally, with the exception of Greater China, for $3,500. The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the assets acquired was concentrated in a single identified asset. The payment was recorded in research and development within the unaudited condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2021. Additionally, there are payments due upon the achievement of certain milestones including $1,750 for preclinical milestones, $19,000 for development milestones, $44,000 for regulatory milestones and $110,000 for sales milestones.

Recently Issued Accounting Pronouncements

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. We will no longer be an emerging growth company as of December 31, 2021, after which we will not be able to take advantage of the reduced disclosure requirements applicable to emerging growth companies. As a result, we expect to adopt this standard on a modified retrospective basis on December 31, 2021 and to reflect the adoption as of January 1, 2021 in our annual results for the period ended December 31, 2021.

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. We will no longer be an emerging growth company as of December 31, 2021, after which we will not be able to take advantage of the reduced disclosure requirements applicable to emerging growth companies. As a result, we expect to adopt this standard on a modified retrospective basis on December 31, 2021 and to reflect the adoption as of January 1, 2021 in our annual results for the period ended December 31, 2021, but the Company does not expect a significant impact to its condensed consolidated financial statements.

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 its condensed consolidated financial statements.

4. INVENTORY

Inventory, net consisted of the following:

	As of	
	September 30, 2021	December 31, 2020
Raw materials	$ 1,023	$ 396
Work in process	2,424	2,660
Finished goods	1,798	941
Inventory, gross	5,245	3,997
Reserve for obsolescence	(440)	(174)
Total inventory, net	$ 4,805	$ 3,823

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 the remaining useful life was 8.00 years as of September 30, 2021. 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 the remaining useful life was 8.00 years as of September 30, 2021. Amortization expense was $4,573 and $1,867 for the three months ended September 30, 2021 and 2020, respectively, and $13,781 and $5,560, for the nine months ended September 30, 2021 and 2020, respectively, and is recorded in general and administrative expenses on the unaudited condensed consolidated statements of operations and comprehensive income (loss).

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

Years ending December 31,	
2021 (excluding the nine months ended September 30, 2021)	$ 4,643
2022	18,570
2023	18,570
2024	18,570
2025	18,570
Thereafter	69,639
Total	$ 148,562

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

	As of	
	September 30, 2021	**December 31, 2020**
Gross Carrying Amount	$ 175,000	$ 175,000
Accumulated Amortization	(26,438)	(12,657)
Net Book Value	$ 148,562	$ 162,343

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. The Company incurred $13,202 and $7,297 for the three months ended September 30, 2021 and 2020, respectively, and $34,561 and $16,574 for the nine months ended September 30, 2021 and 2020, respectively, for sales-based,

trademark and tiered royalties recognized as cost of product sold. As of September 30, 2021 and December 31, 2020, the Company had accrued $13,202 and $9,006, respectively, for sales-based, trademark and tiered royalties. The Company had $0 and $100,000 accrued for milestone payments to Bioprojet as of September 30, 2021, and December 31, 2020, respectively.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	September 30, 2021	December 31, 2020
Royalties due to third parties	13,202	9,006
Rebates and other sales deductions	15,067	7,803
Interest	2,125	—
Selling and marketing	851	1,905
Research and development	790	2,186
Professional fees, consulting, and other services	1,678	1,081
Other expenses	510	746
Milestone payment	—	100,000
	$ 34,223	$ 122,727

8. DEBT

Credit Agreements

Blackstone Credit Agreement

On August 9, 2021, the Company entered into the Blackstone Credit Agreement that provides for (i) a senior secured term loan facility in an aggregate original principal amount of $200,000 (the “Initial Term Loan”) and (ii) a senior secured delayed draw term loan facility in an aggregate principal amount up to $100,000 (the “DDTL” and, together with the Initial Term Loan, the “Loans”). The DDTL will become available on August 9, 2022.

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

The net cash received related to the Initial Term Loan as a result of the transaction, less debt issuance costs of $8,147, was $191,853. The debt issuance costs related to the Initial Term Loan will be amortized as additional interest expense over the five-year loan term of the Blackstone Credit Agreement. In addition, the Company paid $1,000 in debt issuance costs relating the DDTL, which are recorded in other current assets within the unaudited condensed consolidated balance sheet. The fair value of the Initial Term Loan as of September 30, 2021 was $190,436.

OrbiMed Credit Agreement

On January 9, 2020, the Company entered into a credit agreement with OrbiMed for an aggregate amount of $200,000 (the “OrbiMed Loan”), with a maturity date of 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 connection with the OrbiMed Loan, the Company extinguished its $200,000 multi-draw loan agreement with CRG Servicing LLC (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, the Company recognized a loss on extinguishment of $22,639 within the Company's unaudited condensed consolidated statements of operations for the nine months ended September 30, 2020.

In connection with the Blackstone Credit Agreement, the Company extinguished the OrbiMed Loan, which required a payoff amount of $222,666 consisting of principal repayment, interest, exit fees and a prepayment premium. The Company recognized a loss on extinguishment of $26,146 relating to the OrbiMed Loan within the Company's unaudited condensed consolidated statements of operation for the three and nine months ended September 30, 2021.

Long-term debt, net consists of the following:

	September 30, 2021	December 31, 2020
Liability component - principal	$ 200,000	$ 200,000
Exit fee	—	14,000
Unamortized debt discount associated with the exit fee, debt financing costs and discount with warrant financing (see note 13)	(7,931)	(19,750)
Liability component - net carrying value	192,069	194,250
Less current portion	(2,000)	—
Long term debt, net	$ 190,069	$ 194,250

Future minimum payments relating to long term debt, net as of September 30, 2021 for the periods indicated below consists of the following:

Years ending December 31,	
2021 (excluding the nine months ended September 30, 2021)	$ 500
2022	2,000
2023	2,000
2024	20,000
2025	20,000
Thereafter	155,500
Total	$ 200,000

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Interest on principal balance	$ 5,030	$ 6,655	$ 18,122	$ 19,549
Amortization of deferred financing costs	459	340	1,820	1,020
Total term loan interest expense	$ 5,489	$ 6,995	$ 19,942	$ 20,569

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

In December 2020, the Company entered into an operating lease for approximately thirteen thousand square feet of additional office space in Plymouth Meeting, PA, which expires in May 2024.

The terms of the lease payments provide for rental payments on a monthly basis and on a graduated scale. The Company 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 $420 and $773 for the three and nine months ended September 30, 2021, respectively, compared to $161 and $516 for the three and nine months ended September 30, 2020, respectively. The following table sets forth the lease payment obligations as of September 30, 2021, for the periods indicated below:

Years ending December 31,	
2021 (excluding the nine months ended September 30, 2021)	$ 134
2022	875
2023	892
2024	334
2025	—
Thereafter	—
Total	$ 2,235

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 September 30, 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 September 30, 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 September 30, 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.

In connection with the Blackstone Credit Agreement, on August 9, 2021, the Company sold an aggregate of 1,048,951 shares of our common stock, par value $0.00001 per share, to Blackstone for an aggregate cash consideration of $30,000, or $28.60 per share. This sale did not involve a public offering and was therefore exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D thereunder as a transaction not involving any public offering.

In connection with the OrbiMed warrant (see Note 13) 221,511 shares of the Company's common stock were issued to OrbiMed on September 3, 2021.

12. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

2020 Stock Incentive Plan

In connection with the Company's IPO, the board of directors adopted, and its stockholders approved, the 2020 Incentive Award Plan (the "2020 Plan"), in order to facilitate the grant of cash and equity incentives to directors, employees (including the Company's named executive officers) and consultants of the Company and its subsidiaries. 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).

2017 Stock Incentive Plan

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

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2021:

	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	1,391,803	$ 35.02	
Awards exercised	(268,569)	$ 8.29	
Awards forfeited	(357,617)	$ 23.66	
Awards outstanding—September 30, 2021	5,976,449	$ 21.76	8.28

Stock Appreciation Rights

The following table summarizes SARs activity for the nine months ended September 30, 2021:

	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—September 30, 2021	49,294	$ 9.24	7.54

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2021:

	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—September 30, 2021	60,000	$ 29.03	9.49

As of September 30, 2021 and December 31, 2020, stock awards issued under the 2017 and 2020 Plans of 1,473,881 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 nine months ended September 30, 2020, the Company reversed $2 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	
	September 30, 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)	4.6 - 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 $12.52 and $10.06 on September 30, 2021 and December 31, 2020, respectively.

Stock-Based Compensation

Stock-based compensation expense, net for the three and nine months ended September 30, 2021 and 2020, respectively, was recorded in the unaudited condensed consolidated statements of operations and comprehensive income (loss) in the following line items:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expense	$ 579	$ 141	$ 1,548	$ 310
Sales and marketing expense	852	159	2,248	378
General and administrative expense	3,233	1,030	7,926	1,578
	$ 4,664	$ 1,330	$ 11,722	$ 2,266

Options and RSUs issued under the 2017 Plan and 2020 Plan are included in stockholder's equity, and SARs are included in other non-current liabilities, in the Company's unaudited condensed consolidated balance sheet. As of September 30, 2021, the total unrecognized stock-based compensation expense related to

Options and RSUs was $63,450. Such amount will be recognized in the Company's consolidated statement of operations over a weighted average period of 3.8 years.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan ("ESPP") was adopted by the Company's Board of Directors on April 30, 2021. The ESPP permits eligible employees to purchase shares of the Company's common stock at a 15% discount from the lesser of the fair market value per share of the Company's common stock on the first day of the offering period or the fair market value of the Company's common stock on the purchase date. Funds are collected from employees through after-tax payroll deductions. The total number of shares reserved for issuance under the ESPP was initially 629,805. It is intended that the ESPP meet the requirements for an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. For the three and nine months ended September 30, 2021, there were no shares issued under the ESPP, respectively. The discount on the ESPP for the three and nine months ended September 30, 2021 was $60 and $80, respectively, and is recorded within stock-based compensation expense.

13. WARRANTS

In connection with the OrbiMed Loan, the Company issued warrants (the "Warrants") to OrbiMed on January 9, 2020. Pursuant to the Warrants, OrbiMed could 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 unaudited 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 unaudited 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. In connection with the Blackstone Credit Agreement, the OrbiMed Loan was repaid in fully and the unamortized debt discount related to the Warrants was included in the loss on debt extinguishment (see Note 11). On September 3, 2021, OrbiMed exercised its option to purchase shares of the Company's common stock pursuant to the Warrants, which resulted in the net settlement of 221,511 shares of the Company's common stock issued to OrbiMed.

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

The Company has reported a net loss for the three months ended September 30, 2021. The weighted average number of shares utilized for basic and diluted net loss per share attributable to common stockholders are the same for this period because all stock options and warrants have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact.

The Company has reported net income for the nine months ended September 30, 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 its diluted net income per share during the period.

For the three and nine months ended September 30, 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 reported a net loss for the three and nine months ended September 30, 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 and nine months ended September 30, 2020 since the additional income would have an antidilutive impact.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator				
Net (loss) income	$ (9,620)	$ 1,909	$ 11,883	$ (36,736)
Accumulation of dividends on preferred stock	—	(6,013)	—	(26,904)
Net (loss) income available to common shareholders	$ (9,620)	$ (4,104)	$ 11,883	$ (63,640)
Denominator				
Net (loss) income per common share - basic	$ (0.17)	$ (0.14)	$ 0.21	$ (4.15)
Net (loss) income per common share - diluted	$ (0.17)	$ (0.14)	$ 0.20	$ (4.15)
Weighted average number of shares of common stock - basic	57,722,163	30,212,959	57,188,101	15,324,362
Weighted average number of shares of common stock - diluted	57,722,163	30,212,959	58,776,158	15,324,362

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options, SARs, and RSUs to purchase common stock	—	—	1,405,092	—
Warrants	—	—	182,965	—
Total	—	—	1,588,057	—

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options, SARs, and RSUs to purchase common stock	6,085,742	5,051,465	4,680,651	5,051,465
Warrants	—	410,239	—	410,239
Total	6,085,742	5,461,704	4,680,651	5,461,704
Adjustment for warrants	$ —	$ 1,525	$ —	$ 3,109

15. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon Biosciences, LLC (“Paragon”). The related party is an entity that shares common ownership with the Company. In addition, the Chairman of the Company’s board of directors was the President and owner of the entity. The Company incurred $71 and $3,628 for the three months ended September 30, 2021 and 2020, respectively, and $213 and $7,101 for the nine months ended September 30, 2021 and 2020, respectively, in management fee expense and other expenses to this related party, which are included in general and administrative expense in the unaudited 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. In August 2021, the Company paid a $2,300 advisory fee to Paragon in connection with the Blackstone Credit Agreement. $2,000 of this payment was recorded in debt issuance costs as a component of long-term debt, net and $300 was recorded in common stock issuance costs as a component of additional paid-in capital, within the unaudited condensed consolidated balance sheet as of September 30, 2021. As of September 30, 2021 and December 31, 2020, the amount included in prepaid expenses and other assets was $0 and $1, respectively, and there were no amounts due to related parties included in current liabilities.

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

Cautionary Note Regarding Forward-Looking Statements

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

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

- failure to successfully execute our growth strategy, including any delays in our planned future growth;
- our failure to maintain effective internal controls; and
- the impact of government laws and regulations.

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

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

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

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

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

Company Overview

We are a commercial-stage, rare disease pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases who have unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action (“MOA”) specifically designed to increase histamine signaling in the brain by binding to H_3 receptors. In August 2019, WAKIX was approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of excessive daytime sleepiness (“EDS”) in adult patients with narcolepsy, and its U.S. commercial launch was initiated in November 2019. 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 diseases that are mediated through H_3 receptors and histamine signaling. Beyond narcolepsy, we are initially focusing on the treatment of EDS associated with Prader-Willi Syndrome ("PWS") and myotonic dystrophy, otherwise known as dystrophia myotonica ("DM"). In December 2020, we initiated a Phase 2 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. In June 2021, we initiated a Phase 2 clinical trial to evaluate pitolisant for the treatment of EDS, fatigue and cognitive dysfunction in adult patients with DM1 and anticipate topline results in the second half of 2022. In addition to these indications, we intend to further explore pitolisant in other rare neurological diseases in which EDS, fatigue and/or 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 rare neurological diseases and are targeting assets that will allow us to further leverage the expertise and infrastructure that we have successfully built at Harmony so we can optimize the benefit of internal synergies. Consistent with this objective, on August 4, 2021, we acquired HBS-102, a Melanin-concentrating hormone receptor 1 (MCHR1) antagonist previously developed as CSTI-100/ALB-127258(a)/ALB-127258 (the "Compound"), along with intellectual property and other assets related to the development, manufacture, and commercialization of the Compound from ConSynance Therapeutics, Inc. In connection with the acquisition, we made an upfront payment of $3.5 million and will be required to make certain payments upon the achievement of certain development milestones, regulatory milestones, and sales milestones and pay ongoing royalties upon commercialization. We acquired full development and commercialization rights globally, but we have provided a grant-back license to ConSynance for the development and commercialization of the Compound in Greater China. We are currently assessing potential clinical targets for HBS-102 which will inform our development strategy going forward.

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, conducting an Expanded Access Program ("EAP") for pitolisant for appropriate patients with narcolepsy in the United States, preparing and submitting our NDA for pitolisant, gaining NDA approval for WAKIX for the treatment of EDS or cataplexy in adult patients with narcolepsy, and

launching and commercializing WAKIX in the United States. In addition, we have opened INDs for development programs in PWS and DM and have initiated clinical trials in PWS and DM in pursuit of potential new indications in those rare disease patient populations.

Liquidity and Sources of Funding

For the nine months ended September 30, 2021, we generated $214 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 credit agreement (the "Credit Agreement") with OrbiMed Royalty & Credit Opportunities III, LP ("OrbiMed"), and (ii) our credit agreement (the "Blackstone Credit Facility") with Blackstone Alternative Credit Advisors LP ("Blackstone"), (c) proceeds from our initial public offering ("IPO") in August 2020, and (d) proceeds from the sale of common stock to Blackstone.

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 at least 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 pitolisant;
- incur manufacturing costs for WAKIX and any additional product candidates;
- conduct post-approval require studies for WAKIX required by the FDA;
- conduct clinical trials in PWS, DM, and other 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;
- conduct earlier stage research and development activities for HBS-102;
- 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 additional indications for pitolisant, HBS-102, or any additional product candidates that successfully complete clinical development;

- acquire or in-license other assets and technologies; and
- incur additional costs associated with being a public company.

Commercial Launch Metrics

As of September 30, 2021, approximately 40% of unique healthcare professionals ("HCPs") (out of a total of approximately 8,000 HCPs who treat the majority of the diagnosed narcolepsy patient population) have prescribed WAKIX since it became available in November 2019. The average number of patients on WAKIX at September 30, 2021 was approximately 3,500. Additionally, as of September 30, 2021, we have secured and maintained formulary access for approximately 80% of all insured lives (Commercial, Medicare and Medicaid) in the United States. Within these covered lives, we have continued to observe additional favorable access to WAKIX for type 1 narcolepsy patients subsequent to the expanded approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020.

COVID-19 Business Update

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

Despite our response strategy, the COVID-19 pandemic has had an effect on our business and the pharmaceutical industry in general. Although the pandemic has impacted the way stakeholders interact with one another, we have leveraged technology and virtual engagement initiatives to offset our reduced in-person access to HCPs. The COVID-19 pandemic also led to high unemployment and corresponding loss of medical insurance for many patients, caused a change in relationship dynamics between patients and their HCPs, and impacted the way patients took, or did not take, their medication. As a result, we were not able to adequately gauge our growth rate and believe that our growth may be adversely impacted in the future if there is a reemergence or future outbreak of COVID-19, including any COVID-19 variant.

We intend to maintain meaningful engagement, generate awareness and educate our patients, HCPs and payors to support our commercial launch performance.

Commercialization

With respect to our commercialization activities, we believe the COVID-19 pandemic has put pressure on top-line prescription demand for WAKIX, primarily due to (i) our field sales team's reduced ability to access HCPs in person, and (ii) fewer patients seeing HCPs for prescriptions or treatments. The impact on demand for WAKIX may have also been related to a reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, the reduced ability to see patients due to (i) cancelled appointments and (ii) the reprioritization of healthcare resources toward the treatment of COVID-19, both of which lead to fewer prescriptions. Despite these challenges, we continued to engage and educate HCPs virtually on the overall benefit/risk profile of WAKIX and continued to provide support for people living with narcolepsy. As offices, clinics and institutions have increased in-person interactions pursuant to health authority and local government guidelines, our field teams are re-initiating in-person interactions with HCPs and customers, but the timing and level of engagement may vary by account and region and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19, including the rise of variants, may occur. Although we are beginning to see increased access to HCPs for our sales team and the economy is beginning to open up, we are still in a transition phase and expect continued, but decreasing, pressure on top line demand in future quarters as the challenges presented by COVID-19 begin to subside.

During the pandemic, elevated unemployment and the corresponding loss of health insurance caused some eligible patients to shift from commercial insurance to free drug and patient assistance programs, which impacted our ability to convert demand into revenue. Given the high unemployment rates and resulting loss of

employer-sponsored insurance coverage, some patients also shifted from commercial payor coverage to government payor coverage, which may have impacted, and may continue to impact, our net revenue.

Supply Chain

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

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

Research and Development

The COVID-19 pandemic has negatively impacted the pharmaceutical industry's ability to conduct clinical trials. As a result of some challenges that we have experienced due to the COVID-19 pandemic, we have taken measures and put contingency plans in place in order to advance our clinical development programs. We implemented remote and virtual approaches to clinical trials, including using telemedicine for remote clinic visits to perform efficacy assessments and sending out licensed HCPs to each patient to collect safety assessments (e.g. labs, electrocardiograms) as required by the protocols. We performed and continue to perform remote site visits and data monitoring where possible. These measures were instituted with the intent of maintaining patient safety and trial continuity while preserving study integrity. One unique challenge we continue to face is the ability to access sleep labs during the COVID-19 pandemic in order to conduct objective sleep testing, which is required for some of our clinical trials. In addition, we rely on contract research organizations ("CROs") or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. In addition, the COVID-19 pandemic has resulted in a significant increase in FDA workload as well as the need to reprioritize the projects under review. As a result, we may experience delays in FDA timelines along the course of the regulatory process (e.g. milestone meetings) and PDUFA action dates. If there is a subsequent outbreak of COVID-19 or any variant thereof or if it reemerges for an extended period of time in the future, we may experience significant delays in our clinical development timelines, which would. adversely affect our business, financial condition, results of operations and growth prospects.

Corporate Development and Other Financial Impacts

The COVID-19 pandemic evolved rapidly and caused a significant disruption of domestic and global financial markets. In addition, the pandemic limited our ability to conduct in-person due diligence and other interactions to identify new opportunities. If there is a subsequent outbreak of COVID-19 or any variant thereof or if it reemerges for an extended period of time, we may be unable to access additional capital, which could negatively affect our ability to execute on certain corporate development transactions or other important investment opportunities.

The COVID-19 pandemic has also affected, and may continue to affect, our business operations and financial results. The extent of the impact of the COVID-19 pandemic or the potential impact of a reemergence or outbreak of the pandemic on our ability to generate sales of, and revenues from, our approved products, our clinical development and regulatory efforts, our corporate development objectives and the value of and market

for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time.

Corporate Responsibility Impact

We have provided support with relief efforts to our local communities, patient-focused organizations and other charitable organizations during the COVID-19 pandemic, including corporate donations, food and medical supplies and other resources. For the safety and well-being of our employees, consultants and their families, we have abided by government-issued work-from-home orders during the COVID-19 pandemic. As COVID-19 cases decrease and more individuals are vaccinated, we intend to resume an in-office flexible work schedule. We will continue to clean and sanitize our offices on a regular basis, and adhere to CDC guidelines.

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.

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.

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 and our clinical development team to identify potential clinical trial sites. Research and development costs are expensed as incurred. We have significantly increased our research and development efforts as we advance our clinical programs in PWS 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;
- costs related to packaging and labeling clinical supplies;
- 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, we do not track research and development expenses on an indication-by-indication basis. A significant portion of our research and development costs are external costs, such as fees paid to CROs and CMOs, central laboratories, contractors, and consultants in connection with our clinical development programs. Internal expenses primarily relate to personnel who are deployed across multiple programs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, milestone payments, and the cost of submitting an NDA to the FDA (and/or other regulatory authorities). We expect our research and development expenses to be significant over the next several years as we advance our current clinical development programs and prepare to seek regulatory approval for additional indications for pitolisant, HBS-102, 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, including any future resurgence, 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 any new product candidate is approved;
- 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 any new 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 September 30, 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 our credit agreements.

Other Expense, Net

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

Interest Expense, net

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

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands)		(In thousands)	
Net product revenue	$ 80,732	$ 45,609	$ 214,227	$ 103,454
Cost of product sales	14,604	7,890	37,701	17,820
Gross profit	66,128	37,719	176,526	85,634
Operating expenses:				
Research and development	11,739	4,230	22,916	11,829
Sales and marketing	16,480	12,601	49,009	38,297
General and administrative	16,856	10,508	45,704	26,280
Total operating expenses	45,075	27,339	117,629	76,406
Operating income	21,053	10,380	58,897	9,228
Loss on debt extinguishment	(26,146)	—	(26,146)	(22,639)
Other expense, net	—	(1,525)	(15)	(3,071)
Interest expense, net	(5,429)	(6,946)	(19,783)	(20,254)
Net (loss) income before provision for income taxes	(10,522)	1,909	12,953	(36,736)
Income tax benefit (expense)	902	—	(1,070)	—
Net (loss) income	$ (9,620)	$ 1,909	$ 11,883	$ (36,736)

Net Product Revenue

Net product revenue increased by $35.1 million, or 77.0%, for the three months ended September 30, 2021 and $110.8 million, or 107.1%, for the nine months ended September 30, 2021 compared to the same periods in 2020. The increase for both comparable periods 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 $6.7 million, or 85.1%, for the three months ended September 30, 2021 and $19.9 million, or 111.6%, for the nine months ended September 30, 2021 compared to the same periods 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 $7.5 million, or 177.5%, for the three months ended September 30, 2021 and $11.1 million, or 93.7%, for the nine months ended September 30, 2021 as compared to the same periods in 2020. The increase for both comparable periods was primarily due to $3.5 million asset acquisition of HBS-102, clinical development work associated with PWS and DM and an increase to stock compensation associated with new awards.

Sales and Marketing Expenses

Sales and marketing expenses increased by $3.9 million, or 30.8% for the three months ended September 30, 2021 and $10.7 million, or 28.0%, for the nine months ended September 30, 2021 as compared

to the same periods in 2020. The increase for both comparable periods was primarily due to patient engagement and marketing activities and an increase to stock-compensation expense associated with new awards.

General and Administrative Expenses

General and administrative expenses increased by $6.3 million, or 60.4% for the three months ended September 30, 2021 and $19.4 million, or 73.9%, for the nine months ended September 30, 2021 as compared to the same periods 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, an increase to stock compensation associated with new awards, and the additional cost of public company insurance, offset by fees paid to Paragon. Additionally, general expenses have increased due to an increase in headcount year-over-year as well as additional spend in 2021 following the COVID-19 pandemic in 2020.

Loss on Debt Extinguishment

Loss on debt extinguishment increased $26.1 million, or 100%, for the three months ended September 30, 2021 and increased $3.5 million, or 15.5%, for the nine months ended September 30, 2021 as compared to the same period in 2020. The three month increase was due to costs of extinguishment of debt during the period related to the prepayment of the OrbiMed Loan Agreement. The nine month increase was due increased costs relating to the OrbiMed debt extinguishment as compared to the extinguishment of debt pertaining to the Loan Agreement with the multi-draw loan with CRG Servicing LLC (the "CRG Loan"), which occurred in 2020.

Other Expense, Net

Other expense decreased by $1.5 million, or 100.0%, for the three months ended September 30, 2021 and $3.1 million, or 99.5% for the nine months ended September 30, 2021, as compared to the same periods in 2020. This is primarily due to the change in the fair value of the warranty liability in 2020.

Interest Expense, Net

Interest expense decreased by $1.5 million, or 21.8%, or the three months ended September 30, 2021 and $0.5 million, or 2.3%, for the nine months ended September 30, 2021, as compared to the same period in 2020 primarily due to lower interest rates as a result of entering into the Blackstone Credit Agreement in August 2021, partially offset by an increase in amortization of deferred financing costs.

Income Taxes

For interim periods, we estimate the annual effective income tax rate and apply the estimated rate to the year-to-date income or loss before income taxes. The effective income tax rate was 8.3% and 0.0% for the nine months ended September 30, 2021 and 2020, respectively. Currently, we have recorded a full valuation allowance against our net deferred tax assets, primarily related to federal and state net operating losses.

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock; (b) borrowings under our (i) CRG Loan, (ii) our Credit Agreement with OrbiMed and (iii) our Blackstone Credit Agreement; (c) the proceeds from our IPO; and (v) the proceeds from the sale of common stock to Blackstone. From our inception through September 30, 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 September 30, 2021, we had cash, cash equivalents and restricted cash of $190.5 million and accumulated deficit of $476.3 million. As of September 30, 2021, we had outstanding debt, net of issuance costs, of $192.1 million.

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

We believe that our anticipated cash from operating and financing activities, including as a result of potential availability under the DDTL (defined below), and existing cash and cash equivalents will enable us to meet our operational liquidity needs and fund our planned investing activities for the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect. See "—Overview—Liquidity and Sources of Funding."

Blackstone Credit Agreement

On August 9, 2021, the Company entered into the Blackstone Credit Agreement that provides for (i) a senior secured term loan facility in an aggregate original principal amount of $200.0 million (the "Initial Term Loan") and (ii) a senior secured delayed draw term loan facility in an aggregate principal amount up to $100.0 million (the "DDTL" and, together with the Initial Term Loans, the "Loans"). The DDTL will become available on August 9, 2022. We used substantially all of the proceeds from the Blackstone Credit Agreement, and the related sale of our common stock, to repay the balance of the OrbiMed Loan.

The repayment schedule for the Initial Loan consists of quarterly $0.5 million principal payments commencing on December 31, 2021 and increasing to quarterly $5 million payments beginning on March 31, 2024, with a $145.5 million payment due on the maturity date of August 9, 2026 ("Maturity Date"). Interest is payable quarterly commencing on November 9, 2021 and continuing through the Maturity Date. The Initial Loan bears interest at a per annum rate equal to LIBOR, subject to a 1.00% floor, plus 6.50%.The Loans are and will be guaranteed by our subsidiary Harmony Biosciences, LLC and certain of our future subsidiaries that are required to become a party thereto as guarantors.

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

OrbiMed Credit Agreement

On February 28, 2019, we entered into the CRG Loan 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 CRG Loan. 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.

Agreement Related to Intellectual Property

In August 2021, the Company entered into an asset purchase agreement with ConSynance Therapeutics, Inc. to acquire HBS-102 (formerly “CSTI-100”), a potential first-in-class molecule with a novel mechanism of action. Under the terms of the agreement, the Company acquired full development and commercialization rights globally, with the exception of Greater China, for $3.5 million, which was recorded in research and development within the accompanying unaudited condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2021. Additionally, there are payments due upon the achievement of certain milestones including $1.8 million for preclinical milestones, $19 million for development milestones, $44 million for regulatory milestones and $110 million for sales milestones.

Recent Milestone Payment

Upon FDA approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy in October 2020 (the “Cataplexy Milestone Trigger Date”), we became obligated to make the $100.0 million milestone payment (the “Cataplexy Milestone Payment”) to Bioprojet 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 September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
Selected cash flow data	(In thousands)	
Cash provided by (used in):		
Operating activities	$ 61,024	$ (13,032)
Investing activities	(100,298)	(2)
Financing activities	347	210,317

Operating Activities

Net cash provided by operating activities for the nine months ended September 30, 2021 consisted of our net income of $11.8 million adjusted for non-cash items of $26.1 million related to loss on extinguishment of debt, $14.0 million related to intangible amortization and depreciation and $11.7 million related to stock-based compensation expense. Net working capital excluding cash decreased by $4.6 million.

Net cash used in operating activities for the nine months ended September 30, 2020 consisted of our net loss of $36.7 million adjusted for non-cash items of $22.6 million associated with loss on extinguishment of debt and $8.7 million related to intangible amortization and fair value of warrants. Net working capital excluding cash decreased by $11.2 million due to company growth and the commercial launch of WAKIX.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2021 was $100.3 million, which was primarily attributable to the $100.0 million milestone payment associated with the Bioprojet License Agreement. There were no significant investing activities for the nine months ended September 30, 2020.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 was $0.3 million, which primarily consisted of $190.9 million in proceeds associated with the Blackstone Credit Agreement, net of issuance costs, and $29.7 million in proceeds associated with issuance of common stock to Blackstone, net of issuance costs. These proceeds were partially offset by $222.0 million in payments of principal and exit fees associated with the extinguishment of the OrbiMed Credit Agreement.

Net cash provided by financing activities for the nine months ended September 30, 2020 was $210.3 million, which primarily consisted of $194.2 million associated with the OrbiMed Credit Agreement net of issuance costs and net proceeds from our IPO of $135.4 million, offset with $120.6 million of repayment and exit fees associated with the CRG Loan.

Off-Balance Sheet Arrangements

For the nine months ended September 30, 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 unaudited condensed consolidated financial statements for recent accounting pronouncements.

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. We will no longer be an ECG as of December 31, 2021, after which we will not be able to take advantage of the reduced disclosure requirements applicable to an ECG.

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 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 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	**$ (9,620)**	**$ 1,909**	**$ 11,883**	**$ (36,736)**
Non-GAAP Adjustments:				
Interest expense	5,429	6,946	19,783	20,254
Taxes	(902)	—	1,070	—
Depreciation	99	100	299	294
Amortization	4,573	1,867	13,781	5,560
EBITDA	(421)	10,822	46,816	(10,628)
Additional Non-GAAP Adjustments:				
Stock-based compensation expense	4,664	1,330	11,722	2,266
Loss on debt extinguishment	26,146	—	26,146	22,639
Warrant expense	—	1,525	—	3,109
Non-GAAP adjusted net income	$ 30,389	$ 13,677	$ 84,684	$ 17,386
Accumulation of yield on preferred stock	—	(6,013)	—	(26,904)
Non-GAAP adjusted net income (loss) available to common stockholders	30,389	7,664	84,684	(9,518)
GAAP reported net (loss) income per diluted share	**$ (0.17)**	**$ (0.14)**	**0.20**	**$ (4.15)**
Non-GAAP adjusted net income (loss) per diluted share	$ 0.51	$ 0.25	1.44	$ (0.62)
Weighted average number of shares of common stock used in non-GAAP diluted per share (1)	59,270,603	30,212,959	58,776,158	15,324,362

(1) The difference in diluted shares compared to the US GAAP computation for the three months ended September 30, 2021, is because all stock options and warrants have been excluded from the computation of diluted weighted-average shares outstanding. See Note 14 to the unaudited condensed consolidated financial statements.

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 September 30, 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 September 30, 2021, we had $200.0 million in borrowings outstanding. The term loan bears interest at an interest rate equal to LIBOR (subject to a 1.00% floor) plus 6.50%. Based on the $200.0 million of principal outstanding as of September 30, 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 and nine months ended September 30, 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 September 30, 2021. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 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 September 30, 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.

Investing ***in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties set forth in our Annual Report on Form 10-K, as well as described below and the other information included or incorporated by reference in this Quarterly Report on Form 10-Q before making an investment in our common stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Part I—Management's Discussion and Analysis of Financial Condition and Results of Operations—Cautionary Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.***

Our Blackstone Credit Agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our Blackstone Credit Agreement contains certain restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event that, we or our subsidiaries 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, make certain acquisitions, 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, or change our name, location, or executive office without notice. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lenders, or in certain cases Blackstone on their behalf, or prepay the outstanding amount under the Blackstone Credit Agreement. The Blackstone Credit Agreement also contains a financial covenant that requires us to maintain at all times cash and cash equivalents in certain deposit accounts in an amount at least equal to $10.0 million.

Our obligations under the Blackstone Credit Agreement are secured by all of our assets, with certain exceptions. We may not be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the Blackstone Credit Agreement. Furthermore, our future working capital, borrowings or equity financing could be unavailable to repay or refinance the amounts outstanding under the Blackstone Credit Agreement. In the event of a liquidation, the lenders under the facility would be repaid all outstanding principal and interest prior to distribution of assets to unsecured creditors, and the holders of our common stock would receive a portion of any liquidation proceeds only if all of our creditors then existing, including the lenders under the Blackstone Credit Agreement, were first repaid in full.

Our failure to comply with the covenants or other terms of the Blackstone Credit Agreement, including as a result of events beyond our control, could result in a default under the Blackstone Credit Agreement that could materially and adversely affect the ongoing viability of our business.

Blackstone and the other Lenders may elect to accelerate the repayment of all unpaid principal of the Loans, accrued interest and other amounts owed under the Blackstone Credit Agreement upon consummation of a specified change of control transaction or the occurrence of certain events of default (as specified in the Blackstone Credit Agreement), including, among other things:

- our default in a payment obligation under the Blackstone Credit Agreement;
- our breach of the restrictive covenants or other terms of the Blackstone Credit Agreement;
- our breach of reporting obligations;
- our failure to properly maintain the collateral;

- the termination or materially adverse amendment of a permit or authorization related to one of our products that is not revoked within 90 days;
- a specified change of control transaction occurring under the License Agreement;
- with respect to WAKIX or another material product, a governmental authority (i) asserting that such product lacks a material authorization, which assertion is not withdrawn or resolved within 90 days or (ii) taking certain regulatory actions resulting in a discontinuance, withdrawal or delay of such product which would reasonably be expected to last for more than 90 days;
- a recall that would reasonably be expected to result in a material adverse effect;
- our entry into a settlement agreement with a government authority resulting in liability greater than $2.0 million;
- our material breach under or the early termination of one of our key intellectual property licensing or supply chain agreements; and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Blackstone Credit Agreement, all amounts outstanding with respect to the Loans (principal and accrued interest), as well as any applicable prepayment premiums or interest "make-whole" payments, would become due and payable, and upon the occurrence of a payment event of default and following acceleration of the Loans, all past due obligations shall bear interest at a default interest rate that is 2.00% higher than the otherwise applicable rate. Our assets or cash flow may not be sufficient to fully repay our obligations under the Loans if the obligations thereunder are accelerated upon any events of default. Further, if we are unable to repay, refinance or restructure our obligations under the Loans, the Administrative Agent on behalf of the Lenders could proceed to protect and enforce their rights under the Blackstone Credit Agreement and other loan documents by exercising such remedies (including foreclosure on the assets securing our obligations under the Blackstone Credit Agreement and the other loan documents) as are available to the Administrative Agent and the Lenders and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Blackstone Credit Agreement or other loan documents or in aid of the exercise of any power granted in the Blackstone Credit Agreement or other loan documents. Such repayment could have a material adverse effect on our business, operating results and financial condition.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. Furthermore, our Blackstone Credit Agreement contains negative covenants that limit our ability to pay dividends.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Amended and Restated Certificate of Incorporation of Harmony Biosciences Holdings, Inc.	8-K	August 21, 2020	3.1
3.2	Amended and Restated Bylaws.	8-K	August 21, 2020	3.2
10.1	Credit Agreement, dated as of August 9, 2021, among Harmony Biosciences Holdings, Inc., as Borrower, Harmony Biosciences, LLC, as Guarantor, the Guarantors from time to time party thereto, the Lenders from time to time party thereto, and Wilmington Trust, National Association, as Administrative Agent.	10-Q	August 10, 2021	10.2
10.2	Pledge and Security Agreement, dated as of August 9, 2021, among Harmony Biosciences Holdings, Inc. and Harmony Biosciences, LLC, as Grantors, the other Grantors from time to time party thereto and Wilmington Trust, National Association, as Administrative Agent.	10-Q	August 10, 2021	10.3
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 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.			
104*	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101)			

* Filed herewith.

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

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

By:	/s/ John C. Jacobs
Name:	John C. Jacobs
Title:	President, Chief Executive Officer and Director (principal executive officer)
Date:	November 9, 2021

By:	/s/ Sandip Kapadia
Name:	Sandip Kapadia
Title:	Chief Financial Officer (principal financial officer)
Date:	November 9, 2021

Exhibit 31.1

Certification of Principal Executive Officer

I, John C. Jacobs, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

By: /s/ John C. Jacobs
John C. Jacobs

Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Sandip Kapadia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

(3)

Date: November 9, 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.

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 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.