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, 2020

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: 1-39450

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, 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

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 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 ☒

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Number of Shares of Common Stock, par value $0.00001 value per share, outstanding on November 9, 2020 was 56,889,111.

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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, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 221,740	$ 24,457
Trade receivables, net	16,326	4,255
Inventory, net	2,311	1,088
Prepaid expenses	4,240	1,436
Other current assets	5,625	261
Total current assets	250,242	31,497
NONCURRENT ASSETS:		
Property and equipment, net	1,038	1,330
Restricted cash	750	750
Intangible asset, net	66,625	72,185
Other noncurrent assets	1,418	941
Total noncurrent assets	69,831	75,206
TOTAL ASSETS	$ 320,073	$ 106,703
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Trade payables	$ 9,347	$ 6,360
Accrued compensation	5,243	7,917
Accrued expenses	17,200	5,500
Other current liabilities	—	115
Total current liabilities	31,790	19,892
NONCURRENT LIABILITIES:		
Deferred rent	305	287
Long term debt, net	192,858	97,946
Other noncurrent liabilities	571	163
Total noncurrent liabilities	193,734	98,396
TOTAL LIABILITIES	225,524	118,288
COMMITMENTS AND CONTINGENCIES (Note 9)		
CONVERTIBLE PREFERRED STOCK		
Convertible preferred stock, net of placement costs		
Series A convertible preferred stock - $1.00 stated value; 0 shares and 286,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 285,000,000 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	348,203
Series B convertible preferred stock - $1.25 stated value; 0 shares and 8,030,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 8,000,000 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	12,023
Series C convertible preferred stock - $1.96 stated value; 0 shares and 25,600,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 25,510,205 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	51,051
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock - $0.00001 par value; 10,000,000 shares and 0 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding at September 30 2020 and December 31, 2019	—	—
Common stock—$0.00001 par value; 500,000,000 shares and 423,630,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 56,888,625 shares and 7,787,470 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	—
Additional paid in capital	582,535	—
Accumulated deficit	(487,987)	(422,862)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	94,549	(422,862)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 320,073	$ 106,703

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,	
	2020	2019	2020	2019
Net product revenues	$ 45,609	$ —	$ 103,454	$ —
Cost of product sold	7,890	—	17,820	—
Gross profit	37,719	—	85,634	—
Operating expenses:				
Research and development	4,230	4,336	11,829	62,319
Sales and marketing	12,601	12,908	38,297	27,477
General and administrative	10,508	12,560	26,280	22,415
Total operating expenses	27,339	29,804	76,406	112,211
Operating income (loss)	10,380	(29,804)	9,228	(112,211)
Loss on debt extinguishment	—	—	(22,639)	—
Other expense, net	(1,525)	—	(3,071)	—
Interest expense, net	(6,946)	(2,095)	(20,254)	(3,326)
Income (loss) before income taxes	1,909	(31,899)	(36,736)	(115,537)
Income taxes	—	—	—	—
Net income (loss) and comprehensive income (loss)	$ 1,909	$ (31,899)	$ (36,736)	$ (115,537)
Accumulation of dividends on preferred stock	(6,013)	(9,027)	(26,904)	(25,656)
Net loss available to common stockholders	$ (4,104)	$ (40,926)	$ (63,640)	$ (141,193)
NET LOSS PER SHARE:				
Basic	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Diluted	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Weighted average number of shares of common stock - basic	30,212,959	7,777,100	15,324,362	7,777,100
Weighted average number of shares of common stock - diluted	30,212,959	7,777,100	15,324,362	7,777,100

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)

	Convertible Preferred Stock Series A, B, & C		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares (1)	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
Conversion 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	—	—	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 (1)	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
Conversion 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	$ 582,535	$ (487,987)	$ 94,549

(1) Common stock of Harmony Biosciences Holdings, Inc.

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

	Convertible Preferred Stock Series A, B, & C		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares (1)	Amount			
Balance as of December 31, 2018	293,000,000	$ 324,201	7,777,100	$ —	$ —	$ (242,673)	$ (242,673)
Net loss	—	—	—	—	—	(115,537)	(115,537)
Issuance of Series C convertible preferred stock, net of issuance costs	25,510,205	48,868	—	—	—	—	—
Preferred stock dividend, Series A	—	24,120	—	—	(1,104)	(23,016)	(24,120)
Preferred stock accretion, Series A	—	2,059	—	—	—	(2,059)	(2,059)
Preferred stock dividend, Series B	—	823	—	—	—	(823)	(823)
Preferred stock accretion, Series B	—	17	—	—	—	(17)	(17)
Preferred stock dividend, Series C	—	712	—	—	—	(712)	(712)
Preferred stock accretion, Series C	—	76	—	—	—	(76)	(76)
Stock-based compensation	—	—	—	—	1,104	–	1,104
Balance as of September 30, 2019	318,510,205	$ 400,876	7,777,100	$ —	$ —	$ (384,913)	$ (384,913)

	Convertible Preferred Stock Series A, B, & C		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares (1)	Amount			
Balance as of June 30, 2019	293,000,000	$ 342,213	7,777,100	$ —	$ —	$ (343,626)	$ (343,626)
Net loss	—	—	—	—	—	(31,899)	(31,899)
Issuance of Series C convertible preferred stock, net of issuance costs	—	48,868	—	—	—	—	—
Preferred stock dividend, Series A	25,510,205	8,040	—	—	(407)	(7,633)	(8,040)
Preferred stock accretion, Series A	—	687	—	—	—	(687)	(687)
Preferred stock dividend, Series B	—	274	—	—	—	(274)	(274)
Preferred stock accretion, Series B	—	6	—	—	—	(6)	(6)
Preferred stock dividend, Series C	—	712	—	—	—	(712)	(712)
Preferred stock accretion, Series C	—	76	—	—	—	(76)	(76)
Stock-based compensation	—	—	—	—	407	—	407
Balance as of September 30, 2019	318,510,205	$ 400,876	7,777,100	$ —	$ —	$ (384,913)	$ (384,913)

(1) Common stock of Harmony Biosciences Holdings, Inc.

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (36,736)	$ (115,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	294	300
Intangible amortization	5,560	965
Milestones associated with acquired in-process research & development (IPR&D)	—	50,000
Stock-based compensation expense	1,870	1,104
Stock appreciation rights market adjustment	396	—
Warrant expense	3,109	—
Noncash paid-in-kind interest expense	—	1,493
Debt issuance costs amortization	1,020	382
Loss on debt extinguishment	22,639	—
Change in operating assets and liabilities:		
Trade receivables	(12,071)	—
Inventory	(1,223)	(916)
Prepaid expenses and other assets	(8,169)	179
Other non-current assets	(476)	75
Trade payables	2,987	7,491
Accrued expenses and other current liabilities	7,738	2,946
Other non-current liabilities	30	69
Net cash used in operating activities	(13,032)	(51,449)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2)	(113)
Milestone associated with acquired in-process research & development (IPR&D)	—	(50,000)
Net cash used in investing activities	(2)	(50,113)
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 preferred stock	—	50,000
Preferred stock issuance costs	—	(1,132)
Proceeds from long term debt	200,000	75,000
Debt issuance costs	(5,804)	(4,309)
Extinguishment of debt	(102,538)	—
Extinguishment of debt exit fees	(18,047)	—
Proceeds from exercised options	283	—
Repurchase of common stock	(167)	—
Tax payments for employees shares withheld	(17)	—
Net cash provided by financing activities	210,317	119,559
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	197,283	17,997
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—Beginning of period	25,207	84,023
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH—End of period	$ 222,490	$ 102,020
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for interest	$ 19,549	$ 108
Cash paid during the year for milestones	—	50,000
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Series A Preferred Stock accrued return	22,780	24,120
Series A accretion of issuance costs	5,562	2,058
Series B Preferred Stock accrued return	777	823
Series B accretion of issuance costs	53	17
Series C Preferred Stock accrued return	3,347	712
Series C accretion of issuance costs	921	76
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

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

The Company

Our operating subsidiary, Harmony Biosciences, LLC, 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 Biosciences, LLC ("Harmony"). The Company is a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs. The Company is headquartered in Plymouth Meeting, Pennsylvania.

Initial Public Offering

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

Reverse Stock Split

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

2. LIQUIDITY AND CAPITAL RESOURCES

The unaudited condensed consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred operating losses and negative cash flows from operations since inception resulting in an accumulated deficit of $487,987 and $422,862, as of September 30, 2020 and December 31, 2019, respectively. As of September 30, 2020, the Company had cash and cash equivalents of $222,490.

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

The Company believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next 12 months from the date of issuance of these unaudited condensed consolidated financial statements.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated balance sheet as of September 30, 2020, condensed consolidated statements of cash flows for the nine months ended September 30, 2020 and 2019, and, condensed consolidated statements of operations and comprehensive income (loss) and the condensed consolidated statements of convertible preferred stock and shareholders' equity (deficit) for the three and nine months ended September 30, 2020 and 2019, are unaudited. The balance sheet as of December 31, 2019 was derived from audited financial statements as of and for the year ended December 31, 2019. 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, 2019, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statements of the Company's financial position as of September 30, 2020, and the results of its operations and its cash flows for the nine months ended September 30, 2019 and 2020. The condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and note disclosures of the Company normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto for the year ended December 31, 2019. The balance sheet data as of December 31, 2019 was derived from the Company's audited financial statements for the year ended December 31, 2019.

Use of Estimates

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

Fair Value of Financial Instruments

The Company's unaudited condensed consolidated financial statements include cash, cash equivalents, accounts payable, and accrued liabilities, all of which are short term in nature and, accordingly, approximate fair value. Additionally, prior to the IPO, the Company's 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 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, 2020	December 31, 2019
Cash and cash equivalents	$ 221,740	$ 24,457
Restricted cash	750	750
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 222,490	$ 25,207

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, 2020, three customers accounted for 100% of gross accounts receivable, Caremark LLC ("CVS Caremark"), which accounted for 33% of gross accounts receivable; PANTHERx Specialty Pharmacy LLC ("Pantherx"), which accounted for 38% of gross accounts receivable; and Accredo Health Group, Inc. ("Accredo"), which accounted for 29% of gross accounts receivable. As of December 31, 2019, two customers accounted for 91% of gross accounts receivable; CVS Caremark, which accounted for 72% of gross accounts receivable, and Pantherx, which accounted for 19% of gross accounts receivable.

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. For the nine months ended September 30, 2019, revenues were zero.

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

Cost of Product Sold

Cost of product sold includes manufacturing and distribution costs, the cost of drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, and salaries of employees involved with production. The Company began capitalizing inventory upon FDA approval of WAKIX® with a portion of the inventory sold during the nine months ended September 30, 2020 produced prior to FDA approval and, therefore, was previously expensed as research and development expense in 2019 in the amount of $1,323. Excluded from cost of product sold shown on the unaudited condensed consolidated statements of operations and comprehensive income (loss) is amortization of acquired developed technology of $1,867 and $5,560 for the three and nine months ended September 30, 2020, respectively.

Advertising Expenses

We expensed the costs of advertising, including promotional expenses, as incurred. Advertising expense was $3,138 and $1,343 for the three months ended September 30, 2020 and 2019, respectively, and was $8,576 and $2,445 for the nine months ended September 30, 2020 and 2019, respectively.

Recently Issued Accounting Pronouncements

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

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

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

4. INVENTORY

Inventory, net consisted of the following:

	As of	
	September 30, 2020	December 31, 2019
Raw materials	$ 185	$ 384
Work in process	1,105	417
Finished goods	1,076	287
Inventory, gross	2,366	1,088
Reserve for obsolescence	(55)	—
Total inventory, net	$ 2,311	$ 1,088

5. INTANGIBLE ASSET

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 which the Company capitalized as an intangible asset and paid in November of 2019. The Company determined a useful life of 10 years for such intangible asset, and, as of September 30, 2020 the remaining useful life was 9 years. The Company expects the annual amortization to be $7,407 for the next five years. Prior to this event, all other milestones associated with the License Agreement were expensed through research and development as they did not meet the criteria to be recognized as an intangible asset.

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

	As of	
	September 30, 2020	December 31, 2019
Gross Carrying Amount	$ 75,000	$ 75,000
Accumulated Amortization	(8,375)	(2,815)
Net Book Value	$ 66,625	$ 72,185

6. LICENSE AGREEMENT

On July 28, 2017, Harmony entered into the License Agreement 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 New Drug Application ("NDA"), which was achieved on February 12, 2019 and was expensed within research and development for the nine months ended September 30, 2019. A milestone payment of $77,000, including a $2,000 fee, 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 payment of $2,000 is due upon the FDA approval of the NDA for WAKIX® for the treatment of cataplexy in adult patients with narcolepsy (the "Trigger Date") which was paid in October 2020 and a $100,000 milestone payment is due within 90 days of the Trigger Date. An additional $40,000 milestone payment is due to Bioprojet upon WAKIX attaining $500,000 in aggregate net sales in the United States. The License Agreement also requires sales-based milestone payments, a fixed trademark royalty and a tiered royalty, all based on net sales, which become due and payable to Bioprojet on a quarterly basis. During the nine months ended September 30, 2020, the Company has incurred $16,574 for sales-based, trademark and tiered royalties recognized as cost of product sold. As of September 30, 2020 and December 31, 2019, the Company had accrued $7,297 and $938, respectively, for sales-based, trademark and tiered royalties.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of	
	September 30, 2020	December 31, 2019
Royalties due to third parties	$ 7,297	$ 938
Rebates and other sales deductions	3,983	713
Research and development	2,119	894
Selling and marketing	1,782	1,547
Professional fees, consulting, and other services	1,881	510
Debt issuance costs	—	638
Employee travel and other expenses	138	260
	$ 17,200	$ 5,500

8. DEBT

Credit Agreements

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

As of December 31, 2019, the Company had borrowed $100,000, resulting in cash proceeds received of $94,816, net of issuance costs. The issuance costs of $5,184 were being amortized over the six-year loan term of the CRG Loan. Unamortized debt issuance costs as of December 31, 2019 are $4,592 and are presented in the unaudited condensed consolidated balance sheets as a direct deduction from the carrying value of the debt.

On January 9, 2020 the Company entered into a credit agreement with OrbiMed Royalty & Credit Opportunities, LP for an aggregate amount of $200,000 (the “OrbiMed Loan”), which matures in January 2026. Borrowings under the OrbiMed Loan are collateralized by all of the Company’s assets, excluding the intellectual property licensed through the License Agreement. The OrbiMed Loan bears an interest rate equal to the sum of (i) the greater of (a) 1-month LIBOR or (b) 2.00% per annum, plus (ii) 11.00% per annum, paid in cash monthly in arrears on the last day of each month starting in January 2020. In addition to entering into the OrbiMed Loan, the Company extinguished the CRG Loan which required a payoff amount of $120,893 consisting of principal repayment, interest, and exit fees. In connection with extinguishment of the CRG Loan, we recognized a loss on extinguishment of $22,639, which included an exit fee of $18,047 and the write-off of the remaining unamortized debt issuance costs of $4,592. The loss on extinguishment of debt was recorded in loss on debt extinguishment within the Company’s unaudited condensed consolidated statements of operations. The net cash received as a result of the transaction, less debt issuance costs of $5,778, was $73,313. These debt issuance costs will be amortized as additional interest expense over the six-year loan term of the OrbiMed Loan. The fair value of the OrbiMed loan as of September 30, 2020 was $210,400.

In connection with the OrbiMed Loan, the Company issued warrants (the “Warrants”) to OrbiMed Royalty & Credit Opportunities, LP on January 9, 2020. See Note 13 for further discussion of the Warrants. Pursuant to the Warrants, OrbiMed Royalty & Credit Opportunities, LP, may purchase up to 410,239 shares of the Company’s Common Stock for an initial exercise price of $16.10 at any time from the date of execution of the Warrants through the expiration date, defined within the Warrants as the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization. The fair value of the Warrants using the Black-Scholes option-pricing model was $2,359 at January 9, 2020. The portion of the OrbiMed Loan proceeds allocated to the warrant liability resulted in a debt discount, which is presented in the 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. The unamortized debt discount as of September 30, 2020 is $2,064 and is presented in the unaudited condensed consolidated balance sheets as a direct deduction from the carrying value of the debt.

The balances of the OrbiMed Loan as of September 30, 2020 and the CRG Loan as of December 31, 2019 were as follows:

	September 30, 2020	December 31, 2019
Liability component - principal	$ 200,000	$ 102,538
Debt discount associated with warrant financing	(2,064)	—
Deferred financing cost	(5,078)	(4,592)
Liability component - net carrying value	$ 192,858	$ 97,946

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

	For the three months ended		For the nine months ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Interest on principal balance	$ 6,655	$ 1,449	$ 19,549	$ 2,488
Interest on PIK	—	870	—	1,493
Amortization of deferred financing costs	340	185	1,020	382
Total term loan interest expense	$ 6,995	$ 2,504	$ 20,569	$ 4,363

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.

During 2018 and 2019 the Company was involved in ongoing litigation with its former chief executive officer related to arbitration and the value of vested common shares. On October 24, 2019, the Company reached a settlement resulting in $3,466 of general and administrative expense reflected in the Company's consolidated results of operations for the year ended December 31, 2019.

Lease Agreements

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

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

In November 2019, the Company entered into an operating lease for approximately four thousand square feet of office space in Chicago, IL, which expires in December 2020.

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 $516 for the nine months ended September 30, 2020, compared to $442 for the nine months ended September 30, 2019. The following table sets forth the lease payment obligations as of September 30, 2020, for the periods indicated below:

Years ending December 31,		
2020	$	363
2021		443
2022		443
2023		443
2024		184
Thereafter		—
Total	$	1,876

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 December 31, 2019, 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. As of September 30, 2020, Series A preferred shares and the cumulative unpaid preferred dividends reflect the reverse stock split and conversion to common stock.

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 December 31, 2019, 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. As of September 30, 2020, Series B preferred shares and the cumulative unpaid preferred dividends reflect the reverse stock split and conversion to common stock.

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 December 31, 2019, 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. As of September 30, 2020, Series C preferred shares and the cumulative unpaid preferred dividends reflect the reverse stock split and conversion to common stock.

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 September 19, 2017, Harmony Biosciences II, LLC, was converted to a C corporation named Harmony Biosciences II, Inc., at which point the 7,709,434 outstanding common units of Harmony Biosciences II, LLC, were converted to 7,709,434 common shares of Harmony Biosciences II, Inc.

On September 22, 2017, the Company issued warrants for 1,690,672 common shares, with an exercise price of $0.01 per share, to the holders of the Convertible Notes upon the consummation of an equity financing transaction and these warrants were immediately exercised resulting in the issuance of 1,690,672 common shares and proceeds of $139.

On August 31, 2018, the Company repurchased and canceled 1,623,007 common shares from the former chief executive officer for $3,200.

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.

1,217,285 common shares held by an investor were subject to certain forfeiture provisions that are dependent upon the outcome of certain future events. On November 15, 2019, the Company removed the provision associated with this forfeiture resulting in $8,400 of noncash stock compensation expense reflected in the Company's unaudited condensed consolidated results of operations for the year ended December 31, 2019.

12. STOCK INCENTIVE PLAN AND STOCK-BASED COMPENSATION

Stock Incentive Plan

On August 7, 2017, the Company adopted an equity incentive plan (the "Plan"). Under the 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, or restricted stock.

In connection with the Company's IPO, the board of directors adopted, and its stockholders approved, the 2020 Incentive Award Plan (the "2020 Plan"), in order to facilitate the grant of cash and equity incentives to directors, employees (including the Company's named executive officers) and consultants of the Company and its subsidiaries. Upon the effectiveness of the 2020 Plan, no further grants will be made under the Equity Incentive Plan. However, the Equity Incentive 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 ISOs and NSOs, SARs, restricted stock, dividend equivalents, RSUs and other stock or cash based awards.

Stock options under the Plan and the 2020 Plan have a 10-year contractual term and vest over the vesting period specified in the applicable award agreement (generally five years from the date of grant), at achievement of a performance requirement, or upon change of control (as defined in the applicable plan).

Changes in awards granted under the Plan as of September 30, 2020 and December 31, 2019, are as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Awards outstanding—December 31, 2019	2,375,218	$ 8.22	8.33
Awards issued	2,812,135	$ 23.01	
Awards exercised	(36,003)	$ 8.22	
Awards forfeited	(99,885)	$ 11.07	
Awards outstanding—September 30, 2020	5,051,465	$ 16.40	8.82

As of September 30, 2020 and December 31, 2019, stock awards issued under the Plan of 751,136 and 573,098 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, compared to $4 for the nine months ended September 30, 2019.

Value of Stock Options

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. 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, 2020	December 31, 2019
Dividend yield	0.00 %	0.00 %
Expected volatility	55.00 - 95.80 %	95.30 - 99.30 %
Risk-free interest rate	0.32 - 0.51 %	1.60 - 2.59 %
Lack of marketability discount	0.00 - 20.48 %	26.00 - 31.00 %
Expected term (years)	5.4 - 6.5	6.5

The weighted average per share fair value of awards issued under the Plan was $9.39 and $3.38 in 2020 and 2019, respectively.

Stock-based compensation expense was $1,330 and $2,266 for the three and nine months ended September 30, 2020, compared to $407 and $1,104 for the three and nine months ended September 30, 2019, and 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,	
	2020	2019	2020	2019
Research and development expense	$ 141	$ 75	$ 310	$ 208
Sales and marketing expense	159	112	378	241
General and administrative expense	1,030	220	1,578	655
	$ 1,330	$ 407	$ 2,266	$ 1,104

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

Years Ending December 31,	Stock Compensation Expense
2020	$ 4,687
2021	9,645
2022	9,514
2023	8,541
2024	7,809
2025	5,001

13. WARRANTS

In connection with the OrbiMed Loan, the Company issued Warrants to OrbiMed Royalty & Credit Opportunities, LP on January 9, 2020. Pursuant to the Warrants, OrbiMed Royalty & Credit Opportunities, LP, may purchase up to 410,239 shares of the Company's Common Stock for an initial exercise price of $16.10 at any time from the date of execution of the Warrants through the expiration date, defined within the Warrants as the earlier of (i) January 9, 2027 and (ii) the closing date of a Corporate Reorganization. The fair value of the Warrants using the Black-Scholes option-pricing model was $2,359 on January 9, 2020 and was initially recorded as a warrant liability which was included in warrant liability in the 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. The unamortized debt discount as of September 30, 2020 is $2,064 and is presented in the unaudited condensed consolidated balance sheet as a direct deduction from the carrying value of the debt. During the three and nine months ended September 30, 2020, a loss of $1,525 and $3,109 were recorded in other expense in the unaudited condensed consolidated statements of operations due to the change in the fair value of the warrant liability. See footnote 14 for the fair value of the Warrants.

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

A summary of the changes in the warrant liability for the nine months ended September 30, 2020 is as follows:

Balance, beginning of period	$ —
Fair Value at Issuance	2,359
Change in fair value included in the statement of operations	3,109
Reclassification to equity	(5,468)
Balance, end of period	$ —

14. EARNINGS PER SHARE

For the three and nine months ended September 30, 2020 and 2019, 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.

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 and warrants. In addition, the Company analyzes the potential dilutive effects of the outstanding convertible preferred stock under the 'if-converted' method when calculating diluted earnings per share, in which it is assumed that the outstanding convertible preferred stock converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (treasury stock or 'if converted') as their diluted net income per share during the period.

The Company has reported a net loss for the three and nine months ended September 30, 2020 and 2019, and the 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 adjustments for the warrants have been 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 per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator				
Net income (loss)	$ 1,909	$ (31,899)	$ (36,736)	$ (115,537)
Accumulation of dividends on preferred stock	(6,013)	(9,027)	(26,904)	(25,656)
Net loss available to common shareholders	$ (4,104)	$ (40,926)	$ (63,640)	$ (141,193)
Denominator				
Net loss per common share - basic	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Net loss per common share - diluted	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Weighted average number of shares of common stock - basic	30,212,959	7,777,100	15,324,362	7,777,100
Weighted average number of shares of common stock - diluted	30,212,959	7,777,100	15,324,362	7,777,100

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock options to purchase common stock	5,051,465	2,398,695	5,051,465	2,398,695
Convertible preferred stock	—	37,421,645	—	36,257,953
Warrants	410,239	—	410,239	—
Total	5,461,704	39,820,340	5,461,704	38,656,648
Adjustment for warrants	$ 1,525	$ —	$ 3,109	$ —

15. FINANCIAL INSTRUMENTS

The Company primarily applies the market approach to determine the fair value of financial instruments that are measured at fair value on a recurring basis. There were no changes to its valuation techniques used to determine the fair value of financial instruments during the nine months ended September 30, 2020. The Company's financial assets and liabilities which are measured at fair value on a recurring basis were comprised of cash, cash equivalents, and restricted cash of $222,490 and $25,207 as of September 30, 2020 and December 31, 2019, respectively, based on Level 1 inputs.

The Company estimates the fair value of the warrant liability using the Black-Scholes option-pricing model at each balance sheet date or when specific events occur. As discussed in Note 13, in connection with the Company's IPO the warrant fair value was updated on August 19, 2020 with the change in fair value recorded in current period earnings as other expense in the unaudited condensed consolidated statement of operations and reclassified to equity. During the nine months ended September 30, 2020, a loss of $3,109 was recorded in other expense in the unaudited condensed consolidated statements of operations due to the change in the fair value of the warrant liability.

The range of assumptions used to determine the fair value of the warrant liability through August 19, 2020 were as follows:

Dividend yield	0.0%
Expected volatility	54.2% - 68.8%
Risk-free interest rate	0.17% - 1.56%
Lack of marketability discount	0.0%
Expected term (years)	1 - 4.5

16. RELATED-PARTY TRANSACTIONS

The Company was party to a management agreement for professional services provided by a related party, Paragon. The related party is an entity that shares common ownership with the Company. In addition, the Chairman of the Company's board of directors was the President and owner of the entity. For the three and nine months ended September 30, 2020, the Company incurred $3,628 and $7,101, 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 income (loss) as compared to $1,102 and $3,120 for the three and nine months ended September 30, 2019, respectively. 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 participates in certain transactions with separate related parties that also share common ownership with the Company, primarily related to combined employee health plans. As of September 30, 2020, and December 31, 2019, the amount due to related parties included in current liabilities was $193 and $1,208, respectively, and the amount included in other assets was $1 and $210, respectively.

17. SUBSEQUENT EVENTS

On October 13, 2020, the Company received notice that the FDA approved the NDA for WAKIX® for the treatment of cataplexy in adult patients with narcolepsy. Pursuant to the License Agreement, upon the Trigger Date, the Company has paid Bioprojet $2,000 in October 2020 and will pay a milestone payment to Bioprojet of $100,000 within 90 days of the Trigger Date. Accordingly, the Company plans to make the milestone payment to Bioprojet on or before its due date.

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

Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

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

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

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

Company Overview

We are a commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs. Our product, WAKIX (pitolisant), is a first-in-class molecule with a novel mechanism of action ("MOA") specifically designed to increase histamine signaling in the brain by binding to 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.

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.

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 ("IND") for pitolisant, initiating an Expanded Access Program ("EAP") for pitolisant for appropriate patients 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 initiated or intend to initiate clinical development programs in Prader-Willi Syndrome ("PWS"), myotonic dystrophy, otherwise known as dystrophia myotonica ("DM") and pediatric narcolepsy to pursue potential new indications.

Initial Public Offering

On August 21, 2020, we completed the initial public offering ("IPO") of our common stock, in which we 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 $135.4 million, after deducting underwriting discounts and commissions and offering expenses of approximately $12.2 million. Upon the closing of the IPO, all outstanding shares of our 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 our convertible preferred stock, and warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for a total of 410,239 shares of common stock.

Liquidity and Sources of Funding

For the three and nine months ended September 30, 2020, we generated $45.6 million and $103.5 million of net product revenues, respectively. We have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock, (b) borrowings under (i) our Loan Agreement with CRG and (ii) our Credit Agreement with OrbiMed, and (c) proceeds from our IPO. As of September 30, 2020, we had cash, cash equivalents and restricted cash of $222.5 million and accumulated deficit of $487.9 million. As of September 30, 2020, we had outstanding debt, net of issuance costs, of $192.9 million.

We believe that our anticipated cash from operating and financing activities and existing cash and cash equivalents will enable us to meet our operational liquidity needs and fund planned investing activities for the next 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 "—Liquidity and Capital Resources."

We expect our expenses to increase as we continue to:

- commercialize WAKIX in the United States for the treatment of EDS or cataplexy in adult patients with narcolepsy;
- incur sales and marketing costs to support the commercialization of WAKIX and any additional product candidates;
- pay royalties and make milestone payments to Bioprojet for the license of WAKIX;
- incur manufacturing costs for WAKIX and any additional product candidates;
- implement post-approval requirements related to WAKIX;
- conduct clinical trials in PWS and DM;
- 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;
- hire additional personnel;
- invest in measures to protect and expand our intellectual property;
- incur interest expenses in conjunction with our debt facility;
- seek regulatory approvals for pitolisant or any additional product candidates that successfully complete clinical development;
- conduct additional clinical trials in pursuit of potential new indications for pitolisant; acquire certain ex-U.S. rights for WAKIX from Bioprojet and subsequently seek foreign regulatory approvals for WAKIX in certain of those jurisdictions; 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, 2020, over 2,000 unique healthcare professionals ("HCPs") (out of a total of approximately 8,000 HCPs who treat approximately 90% of diagnosed narcolepsy patients) have prescribed WAKIX since it became available in November 2019. The average number of patients on WAKIX during the third quarter of 2020 was 2,200, representing a 22% increase from the second quarter of 2020. We have secured formulary access for approximately 182 million lives, which represents approximately 80% of our target covered lives, which we define as a group of certain public and private payors that account for approximately 80% of all covered lives in the United States.

COVID-19 Business Update

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

Despite our response strategy, the COVID-19 pandemic is having an effect on our business and the pharmaceutical industry in general, and is impacting the way stakeholders interact with one another during this pandemic. We continue to leverage technology and virtual engagement initiatives to offset our reduced in-person access to HCPs. The COVID-19 pandemic, which has led to high unemployment and corresponding loss of medical insurance, has caused a change in relationship dynamics between patients and their HCPs and has impacted the way patients take, or do not take, their medication. Based on these factors, we expect the revenue growth rate in the fourth quarter of 2020 and possible future quarters may be adversely impacted by the ongoing COVID-19 pandemic.

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

Commercialization

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

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

Supply Chain

We currently expect to have adequate supply of WAKIX through 2021. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the COVID-19 pandemic.

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

Research and Development

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

Corporate Development and Other Financial Impacts

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

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

Corporate Response

We have supported our local communities, patient-focused organizations and other charitable organizations with relief efforts, including corporate donations.

Financial Operations Overview

Revenue

We did not generate any revenue from inception until the fourth quarter of 2019. Our current product, WAKIX, was approved by the FDA for the treatment of EDS in adult patients with narcolepsy in August 2019, became commercially available in November 2019 and was approved by the FDA for the treatment of cataplexy in adult patients with narcolepsy in October 2020. For the three months ended September 30, 2020, we had $45.6 million of net product revenue. For the nine months ended September 30, 2020, we had $103.5 million of net product revenue.

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. For further discussion of the components of Revenue, see "—Critical Accounting Policies and Significant Judgments and 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. A portion of the inventory sold during the three months ended September 30, 2020 was produced prior to FDA approval and, therefore, expensed previously as research and development expense in 2019 in the amount of $1.3 million. Excluded from cost of product sold is amortization of acquired developed technology of $1.9 million and $1.0 million in the three months ended September 30, 2020 and 2019, respectively.

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

The shelf life of our product is three years from date of manufacture, with earliest expiration of current inventory expected to be September 2021. As of September 30, 2020, we expect our existing inventory to have minimal obsolescence. 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 primarily been limited to the license of the rights to pitolisant, the establishment of an 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 a development program for new indications for pitolisant in patients with PWS, DM and pediatric narcolepsy. We also have research and development expenses related to our team of Medical Science Liaisons ("MSLs") who interact with key opinion leaders, with a focus on the science, the role of histamine in sleep-wake state stability and the novel mechanism of action of pitolisant. In addition, our MSLs support our market access team with clinical data presentations to payors upon request. Research and development costs are expensed as incurred. We expect to significantly increase our research and development efforts as we advance our clinical programs in patients with PWS, DM and pediatric narcolepsy, and continue to expand our product-candidate 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 preclinical studies and clinical trials; other third-party expenses directly attributable to the development of our product candidates; and
- amortization expense for assets used in research and development activities.

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

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

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any additional indications for pitolisant or other product candidates that we move forward for regulatory approval. There are numerous risks and uncertainties associated with developing product candidates, including uncertainty related to:

- the duration, costs and timing of clinical trials of our current development programs and any further clinical trials related to new product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- the impact of the COVID-19 pandemic on the ability to initiate new clinical trials and/or maintain the continuity of ongoing clinical trials that could be impacted by future shelter-in-place orders and needs of the health care system to focus on managing patients affected by COVID-19;

- receiving Bioprojet's consent to pursue additional indications for pitolisant;
- the acceptance of INDs for our planned clinical trials or future clinical trials;
- the successful and timely enrollment and completion of clinical trials;
- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- the entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; and
- successfully launching our product candidates and achieving commercial sales, if and when approved.

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

Sales and Marketing Expenses

Our sales and marketing expenses have primarily been limited to the market development and launch activities of WAKIX for the treatment of EDS 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"), entered into on September 22, 2017, 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 terminated the Management Services Agreement upon the consummation of our IPO. In connection with such termination, we paid Paragon a termination fee of $2.6 million.

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. Since entering into the right of use agreement in November 2019 through September 30, 2020, we paid fees of $0.7 million 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 a multi-draw term loan agreement (the "Loan Agreement") with CRG Servicing LLC ("CRG").

Other Income / Expense, Net

Other income / expense, net consists primarily of costs of the fair value of the warrants associated with the credit agreement (the "Credit Agreement") we entered into with OrbiMed Royalty & Credit Opportunities III, LP ("OrbiMed").

Interest Income / Interest Expense

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

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Net product revenue	$ 45,609	$ —	$ 103,454	$ —
Cost of product sales	7,890	—	17,820	—
Gross profit	37,719	—	85,634	—
Operating expenses:				
Research and development	4,230	4,336	11,829	62,319
Sales and marketing	12,601	12,908	38,297	27,477
General and administrative	10,508	12,560	26,280	22,415
Total operating expenses	27,339	29,804	76,406	112,211
Operating income (loss)	10,380	(29,804)	9,228	(112,211)
Loss on debt extinguishment	—	—	(22,639)	—
Other expense, net	(1,525)	—	(3,071)	—
Interest expense, net	(6,946)	(2,095)	(20,254)	(3,326)
Net income (loss) before provision for income taxes	1,909	(31,899)	(36,736)	(115,537)
Provision for income taxes	—	—	—	—
Net income (loss)	$ 1,909	$ (31,899)	$ (36,736)	$ (115,537)

Net Product Revenue

Net product revenue increased by $45.6 million and $103.5 million for the three and nine months ended September 30, 2020, respectively, as compared to the same periods in 2019 due to the commercial launch of WAKIX on November 1, 2019.

Cost of Product Sales

Cost of product sales increased by $7.9 million and $17.8 million for the three and nine months ended September 30, 2020, respectively, as compared to the same period in 2019 due to the commercial launch of WAKIX on November 1, 2019.

Research and Development Expenses

Research and development expenses remained consistent for the three months ended September 30, 2020 as compared to the same period in 2019. Research and development expenses decreased $50.5 million, or 81.0%, for the nine months ended September 30, 2020 as compared to the same period in 2019 primarily due to a milestone payment in February 2019 of $50.0 million associated with the Bioprojet License Agreement upon the acceptance of our NDA for WAKIX by the FDA and an increase in clinical activity.

Sales and Marketing Expenses

Sales and marketing expenses remained consistent for the three months ended September 30, 2020 as compared to the same period in 2019. Sales and marketing expenses increased by $10.8 million, or 39.4% for the nine months ended September 30, 2020, as compared to the same period in 2019 primarily due to field sales force personnel expenses and related field sales operations associated with the commercial launch of WAKIX.

General and Administrative Expenses

General and administrative expenses decreased by $2.1 million, or 16.4% for the three months ended September 30, 2020 as compared to the same period in 2019. This is primarily due to a legal settlement with our former CEO and an extension payment to Bioprojet in 2019 offset by the termination fee in connection with the Management Services Agreement. General and administrative expenses increased by $3.9 million, or 17.2% for the nine months ended September 30, 2020 as compared to the same prior-year period in 2019 primarily due to intangible asset amortization for a full nine months in 2020, the termination fee in connection with the Management Services Agreement and additional fees associated with our IPO in 2020, offset by the legal settlement with our former CEO and an extension payment to Bioprojet in 2019.

Loss on Debt Extinguishment

Loss on debt extinguishment was zero for the three months ended September 30, 2020 compared to the same period in 2019, and increased $22.6 million, or 100%, for the nine months ended September 30, 2020 as compared to the same period in 2019 primarily due to costs of extinguishment of debt during the period related to the prepayment of the Loan Agreement with CRG.

Other Income (Expense), Net

Other income (expense), net increased by $1.5 million, or 100%, and $3.1 million, or 100%, for the three and nine months ended September 30, 2020, respectively, as compared to the same period in 2019 due to the change in the fair value of warrants.

Interest Income (Expense), Net

Interest expense increased by $4.9 million, or 231.6%, and $16.9 million, or 509.0%, for the three and nine months ended September 30, 2020, respectively, as compared to the same period in 2019 primarily due to payment of interest on the outstanding debt facility and amortization of debt issuance costs, partially offset by interest income earned on our cash balances.

Income Taxes

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

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily with (a) proceeds from sales of our convertible preferred stock, (b) borrowings under (i) our Loan Agreement with CRG and (ii) our Credit Agreement with OrbiMed, and (c) the proceeds from our IPO. From our inception through September 30, 2020, 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, 2020, we had cash, cash equivalents and restricted cash of $222.5 million and accumulated deficit of $487.9 million. As of September 30, 2020, we had outstanding debt, net of issuance costs, of $192.9 million.

The unaudited condensed consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred operating losses and negative cash flows from operations since inception resulting in an accumulated deficit of $487.9 million as of September 30, 2020.

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

OrbiMed Credit Agreement

On February 28, 2019, we entered into the Loan Agreement with CRG for an aggregate of $200.0 million of which $102.5 million was outstanding as of December 31, 2019. On January 9, 2020, we entered into the Credit Agreement with OrbiMed for an aggregate of $200.0 million and paid off all of our obligations under the Loan Agreement. Borrowings under the Credit Agreement are collateralized by all of the Company's assets, excluding the intellectual property licensed through the Bioprojet License Agreement. 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.

Upcoming 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. We expect to make the $100.0 million Cataplexy Milestone Payment to Bioprojet on or before its due date.

Cash Flows

The following table presents the major components of net cash flows used in and provided by operating, investing and financing activities for the periods indicated.

	Nine Months Ended September 30,	
	2020	2019
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$ (13,032)	$ (51,449)
Investing activities	(2)	(50,113)
Financing activities	210,317	119,559

Net Cash Used in Operating Activities

Net cash used in operating activities decreased to $13.0 million for the nine months ended September 30, 2020 as compared to $51.4 million for the same period in 2019. This decrease was primarily attributable to company growth associated with the commercial launch of WAKIX.

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 cash used in operating activities for the nine months ended September 30, 2019 consisted of net loss of $115.5 million adjusted for a reclassification of $50.0 million to investing activities related to a milestone payment associated with the Bioprojet License Agreement.

Net Cash Used in Investing Activities

Net cash used in investing activities decreased by $50.0 million to a minor amount for the nine months ended September 30, 2020 as compared to $50.1 million for the same period in 2019. This change was primarily due to $50.0 million of milestone payments associated with the Bioprojet License Agreement.

Net Cash Provided by Financing Activities

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 Agreement.

Net cash provided by financing activities for the nine months ended September 30, 2019 was $119.6 million, which primarily consisted of borrowings under the CRG Loan Agreement net of issuance costs and net proceeds from preferred stock.

Off-Balance Sheet Arrangements

For the three and nine months ended September 30, 2020 and 2019, we did not have, and we do not currently have, any off-balance sheet arrangements.

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 ("U.S. 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 U.S. 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 Agreement 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 U.S. 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. While our accounting policies are more fully described in Note 3 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies" in the final prospectus for our IPO, filed pursuant to Rule 424(b) under the Securities Act with the SEC on August 18, 2020 (the "Prospectus") and the notes to the unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three and nine months ended September 30, 2020, there were no material changes to our critical accounting policies from those discussed in the Prospectus.

Recent Accounting Pronouncements

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

The JOBS Act

We are an “emerging growth company” (“EGC”), as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). 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 completing of this offering, (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.

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, 2020, 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, 2020, we had $200.0 million in borrowings outstanding. The term loan bears interest at an interest rate of the greater of (a) LIBOR or (b) 2.00% per annum, plus 11.00% per annum. Based on the $200.0 million of principal outstanding as of September 30, 2020, 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 ending September 30, 2020 and 2019.

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, 2020. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2020, 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, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the quarter ended September 30, 2020 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 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.

Summary Risks

We are subject to risks related to our financial condition and capital requirements, risks related to our business, risks related to development, regulatory approval and commercialization, risks related to intellectual property, and risks related to being a public company. There are also risks related to ownership of our common stock. Some of our most significant risks include the following:

- We have incurred significant losses for most periods since our inception and may never achieve or maintain profitability.
- We have only recently begun generating revenue from product sales and may never be profitable.
- We have a limited operating history and history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have only limited capital and may need to raise additional capital before we become profitable.
- Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.
- Our auditor has previously expressed substantial doubt about our ability to continue as a going concern and we may be unable to remain a going concern.
- We have made and we may be required to make significant payments in the future to Bioprojet under our licensing and collaboration agreements for pitolisant.
- We are substantially dependent on our ability to successfully commercialize WAKIX, which is currently our only approved product. If we are unable to successfully commercialize WAKIX, our ability to generate revenue and our financial condition will be adversely affected.
- The commercial adoption of WAKIX and any other product candidates we develop will depend on the degree of their market acceptance.
- We rely on our license agreement with Bioprojet to provide rights to the core intellectual property relating to pitolisant, and any termination or loss of significant rights under the agreement would adversely affect our development and/or commercialization of pitolisant.
- The ongoing COVID-19 pandemic may result in disruptions to our commercialization, clinical trials, manufacturing and other business operations, which could have a material adverse effect on our business, financial condition, operating results, cash flows and prospects.

- Because a number of companies compete with us, many of which have greater resources that we do, and because we face rapid changes in science in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.
- The regulatory approval process of the FDA is costly, lengthy and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for pitolisant in other potential indications for which we may seek to develop pitolisant, our business will be substantially harmed.
- If we fail to obtain and sustain an adequate level of coverage and reimbursement for WAKIX and other product candidates by third-party payors, sales would be adversely affected.
- WAKIX has been approved by the FDA for the treatment of EDS or cataplexy in adult patients with narcolepsy. Regulatory approval is limited by the FDA to the specific indications for which approval has been granted and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing pitolisant for other indications. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of pitolisant for unapproved or "off-label" uses, resulting in damage to our reputation and business.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have only recently begun to generate revenue from product sales and have incurred losses in each year since our inception for most periods. Our ability to generate revenue and achieve profitability depends on our ability to successfully commercialize WAKIX for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, and to successfully develop and obtain the regulatory approvals necessary to commercialize pitolisant for other indications. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we commercialize WAKIX and as we continue to develop and potentially commercialize pitolisant for other indications.

We have only recently begun generating revenue from product sales and may never be profitable.

Other than WAKIX, we do not currently have any products that are available for commercial sale, and we may never achieve profitability. Our net loss was $36.7 million and $115.5 million for the nine months ended September 30, 2020 and 2019, respectively, and our net loss was $152.0 million for the year ended December 31, 2019. As of September 30, 2020, we had an accumulated deficit of $487.9 million. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue until we further commercialize WAKIX and obtain regulatory approval for potential additional indications for pitolisant, or any other product candidates we may develop. We generated net product revenues of $103.5 million and zero for the nine months ended September 30, 2020 and 2019 and net product revenues of $6.0 million for the years ended December 31, 2019. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval, including marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have a limited operating history and history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2017, and our operations to date have been largely focused on staffing our company, business planning, raising capital, acquiring the rights to pitolisant, seeking registration in the United States for our product WAKIX, which is approved for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, the commercialization of WAKIX, manufacturing WAKIX on a commercial scale, and preparing to develop pitolisant for other potential indications. This has included preparing the application for regulatory approval and other activities that were required for us to obtain approval of our NDA, and activities related to commercializing WAKIX. WAKIX is our only drug candidate for which we have obtained regulatory approval. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a longer history of successfully developing and commercializing drugs.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors.

We have only limited capital and, may need to raise additional capital before we become profitable.

As of September 30, 2020, we had an accumulated deficit of $487.9 million, and available cash and cash equivalents of $221.7 million. We have $200.0 million of debt outstanding under our Credit Agreement with OrbiMed. We believe that our anticipated cash from operating and financing activities and existing cash and cash equivalents will enable us to meet its operational liquidity needs and fund our planned investing activities for the next 12 months.

This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Because the length of time and activities associated with the successful development of our product candidates is highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities.

To fund future operations to the point at which we are able to generate positive cash flow from sales of WAKIX or other potential product candidates, we may need to raise significant additional capital. The amount and timing of future funding requirements will depend on many factors, including, but not limited to:

- the progress and results of our commercialization of WAKIX;
- the effect of competing technological and market developments;
- the cost and timing of commercial-scale manufacturing activities;
- the payment of royalties and milestone payments to Bioprojet;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other regulatory authorities;
- the willingness of the FDA and other comparable regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for the review and approval of pitolisant for other potential indications or of any other product candidates;
- the potential expansion of our current development programs to seek new indications for pitolisant, potential new development programs for additional indications, and related general and administrative support;
- the initiation, progress, timing, and results of our clinical trials through all phases of development for pitolisant as a treatment for other indications and any other product candidates;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, in-licensed or otherwise;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us for pitolisant or future product candidates;
- the cost of acquiring rights to other pharmaceutical products in the future to further develop and commercialize;
- the cost of general operating expenses;

- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where those product candidates are approved and where we choose to commercialize our products on our own; and
- the costs of operating as a public company.

Other than our Credit Agreement with OrbiMed, we have no committed source of additional capital and we anticipate that we may seek to fund our operations through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. We cannot assure you that anticipated additional financing will be available to us on favorable terms, or at all. Although we have been successful in obtaining financing through the issuance of our equity securities and debt facilities, we cannot assure you that we will be able to do so in the future. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us to fund our commercialization of WAKIX and clinical development and commercialization of pitolisant for other indications, if approved, and other business activities, we could be forced to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or curtail or cease our operations.

Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate sufficient product revenue from the sale of WAKIX, we may need to finance our cash needs through a combination of equity offerings, debt financings, including our Credit Agreement, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely affect our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Our auditor has previously expressed substantial doubt about our ability to continue as a going concern and we may be unable to remain a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited financial statements, we had previously concluded there was substantial doubt regarding our ability to continue as a going concern and the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2019 contained an explanatory paragraph communicating this matter. Our financial statements did not include any adjustments that may have been necessary in the event we were unable to continue as a going concern. Had we been unable to establish to the satisfaction of our independent registered public accounting firm that our expected operational performance and liquidity would be sufficient to allow for the removal of this going concern qualification, we would have needed to significantly modify our operational plans for us to continue as a going concern. We believe that our anticipated cash from operating and financing activities and existing cash and cash equivalents, including the net proceeds from our initial public offering, will enable us to meet our operational liquidity needs and fund our planned investing activities for the next 12 months.

We have made and may be required in the future to make significant payments to Bioprojet under our licensing and collaboration agreements for pitolisant.

Under our agreements with Bioprojet, we are subject to significant obligations, including payment obligations upon the achievement of specified milestones and payments based on product sales, as well as other material obligations. Certain of the milestone payments payable by us under these agreements were paid prior to our commercialization of WAKIX. In addition, we are subject to two further milestone payments pursuant to the Bioprojet License Agreement: (i) a milestone payment of $40.0 million upon the attainment of aggregate net sales of WAKIX in the United States of $500.0 million subsequent to the date of NDA approval by the FDA and (ii) the $100.0 million Cataplexy Milestone Payment, which we became obligated to make upon the Cataplexy Milestone Trigger Date. Upon the Cataplexy Milestone Trigger Date, 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. We expect to make the $100.0 million Cataplexy Milestone Payment to Bioprojet which is due 90 days after the due date. There can be no assurance that we will have the funds necessary to make such payments in the future, or be able to raise such funds when needed, on terms acceptable to us, or at all. If we fail to comply with our payment obligations, Bioprojet has the right to terminate the license agreement, in which event we would not be able to develop, manufacture or market WAKIX or any other pitolisant-based product candidate. Furthermore, if we are forced to raise additional funds to make such payments, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards of approximately $147.8 million and $139.3 million, respectively. Our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”). The limitations apply if we experience an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in the ownership of our equity by certain stockholders over a rolling three-year period. Similar provisions of state tax law may also apply to limit the use of our state net operating loss carryforwards. We have not assessed whether such an ownership change has previously occurred. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing net operating loss carryforwards to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Section 382 of the Code. As a result, if or when we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

Our credit agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our Credit Agreement with OrbiMed contains certain restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event that, 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, or change our name, location, executive office or executive management without notice. We, therefore, may not be able to engage in any of the foregoing transactions unless we obtain the consent of OrbiMed or prepay the outstanding amount under the Credit Agreement. The Credit Agreement also contains certain financial covenants, including minimum revenue and cash balance requirements (which include maintaining minimum liquidity of $12.5 million), and financial reporting requirements.

Our obligations under the Credit Agreement are secured by all of our property, 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 Credit Agreement. Furthermore, our future working capital, borrowings or equity financing could be unavailable to repay or refinance the amounts outstanding under the Credit Agreement. In the event of a liquidation, OrbiMed 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 OrbiMed, were first repaid in full.

Risks Related to Our Business

We are substantially dependent on our ability to successfully commercialize WAKIX, which is currently our only approved product. If we are unable to successfully commercialize WAKIX, our ability to generate revenue and our financial condition will be adversely affected.

Since our inception, we have invested substantially all of our capital resources on the development, registration and commercialization of WAKIX, which was approved for the treatment of EDS in adult patients with narcolepsy in August 2019 and for the treatment of cataplexy in adult patients with narcolepsy in October 2020. We cannot be certain that WAKIX will be successfully commercialized.

Our ability to generate revenue from product sales depends heavily on our success in many areas, including but not limited to:

- successfully commercializing WAKIX, either independently or with marketing service providers;
- the effectiveness of our sales and marketing strategy and operations, and obtaining market acceptance of WAKIX, including garnering market share from existing and future treatment alternatives;
- maintaining compliance with all regulatory requirements applicable to WAKIX and our commercial activities, including the post-marketing requirements and post-marketing commitments required by the FDA;
- obtaining coverage and adequate reimbursement from third-party payors for each of our product candidates;
- the continued acceptability of the safety profile of WAKIX and the occurrence of any unexpected side effects, adverse reactions or misuse, including potential business impact such as the need to withdraw the product (either voluntarily or as mandated by the FDA), loss of support by the advocacy communities or loss of positive corporate reputation resulting in related unfavorable media coverage in these areas;
- successfully managing third-party service providers involved in the manufacturing and development of pitolisant;
- successfully completing the development of pitolisant in other indications by demonstrating safety, tolerability and efficacy profiles that are satisfactory to the FDA;
- obtaining regulatory approvals to market pitolisant for other indications;
- complying with the terms of the license agreement with Bioprojet;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding the portfolio of intellectual property rights, including patents, trade secrets and knowhow; and
- attracting, hiring and retaining qualified personnel.

In our efforts to market WAKIX for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, our revenue will be dependent, in part, on the size of the markets in the United States, or in other territories where we may seek and obtain regulatory approval, the number of competitors in such markets, the acceptance of the price of the product in those markets and the ability to obtain reimbursement at any price. If the number of our addressable patients is not as large as we estimate or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products. If we are not able to generate substantial revenue from the sale of approved products, we may never become profitable.

The commercial adoption of WAKIX and any other product candidates we develop will depend on the degree of their market acceptance.

Even with the requisite approvals from the FDA and other regulatory authorities, the commercial adoption of WAKIX for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, and any other indications and product candidates we may develop, will depend on the degree of their acceptance by physicians, patients, third-party payors and others in the medical community. If WAKIX or any other product candidates we develop do not achieve an adequate level of market acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of WAKIX or any other product candidates we develop, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

- the safety and efficacy of the product as demonstrated in clinical trials;
- the perception of physicians, patients, third-party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality-of-life and cost-effectiveness of the product, compared to those of other available treatments;
- the product's approved labeling, including the description of the product's approved indications, the description of its efficacy, including the endpoints in which it showed an improvement, and the prevalence and severity of any side effects, including any associated limitations or warnings;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to differentiate WAKIX or other approved products from other treatments in the same space;
- the adoption of WAKIX as a first-line therapy for EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy;
- the prevalence and severity of any side effects, including those that may be discovered following approval and commercialization;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the publicity concerning our products or competing products and treatments;
- product liability litigation alleging injuries relating to our products or similar classes of drugs;
- any post-approval study requirements for our products and the results thereof; and
- sufficient third-party insurance coverage and reimbursement.

Our continuing efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits and risks of WAKIX may require significant resources and may never be successful. The adoption of WAKIX could be limited if physicians prescribe it only as a second line therapy. Physicians may opt to prescribe the products of our competitors for a variety of reasons. For example, WAKIX did not demonstrate non-inferiority to modafinil and, as such, physicians and patients may choose modafinil rather than WAKIX. Furthermore, because the clinical response to WAKIX may take several weeks before addressing EDS symptoms, patients and physicians may choose other fast acting, stimulant and wake promoting agents over WAKIX. If WAKIX fails to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

We cannot guarantee that WAKIX or any other product candidates we may seek to develop will ever be commercially successful, and to the extent they are not commercially successful, such product candidates would incur significant expense with no corresponding revenue. Because we expect the sales of WAKIX to generate substantially all of our revenue for the foreseeable future, the failure of WAKIX to find market acceptance would substantially harm our business and could require us to seek additional financing.

The market opportunity for WAKIX or any future product candidate we develop may be smaller than we estimate.

The potential market opportunity for WAKIX and any future product candidate is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions of the current market size and current pricing for commercially available products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. While we believe our estimates are reasonable and reliable, they may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of diseases and disorders. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for WAKIX or any future product candidate we develop may be limited or may not be amenable to treatment with WAKIX or such future product candidate, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We rely on our license agreement with Bioprojet to provide rights to the core intellectual property relating to pitolisant, and any termination or loss of significant rights under the agreement would adversely affect our development and/or commercialization of pitolisant.

We have licensed our core intellectual property relating to pitolisant from Bioprojet. If, for any reason, our license and commercialization agreement with Bioprojet is terminated or we otherwise lose those rights, it would materially adversely affect our business. Pursuant to our license and commercialization agreement, we obtained intellectual property rights in connection with the commercialization of pitolisant in the United States and its territories, commonwealths and protectorates, including Puerto Rico, which includes an exclusive license to use certain intellectual property owned by Bioprojet related to clinically developing and commercializing the pitolisant product candidate for narcolepsy, obstructive sleep apnea, idiopathic hypersomnia and Parkinson's Disease.

Under the license agreement, Bioprojet is responsible for conducting all preclinical studies and clinical trials necessary for achieving and maintaining regulatory approval in the United States for narcolepsy and cataplexy indications, including all costs and expenses. We are responsible for all other costs associated with other development and regulatory activities, unless Bioprojet otherwise agrees to participate in funding such activities. We must obtain consent from Bioprojet before commencing any clinical trials related to pitolisant. Our ability to pursue indications other than the ones specifically enumerated in the license agreement is also contingent on mutual agreement of Bioprojet and us as to those indications and such agreement may be withheld at Bioprojet's discretion. If Bioprojet denies consent for us to conduct clinical trials or pursue any such other indication for any reason, we will not have the right under our license and commercialization agreement to commercialize our product for such indication. In such event, Bioprojet may pursue commercialization of such indication for itself in our territory, or it may license the right to commercialize such indication in our territory to third parties, including our competitors.

Our license and commercialization agreement also imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Bioprojet, and Bioprojet may have the right to terminate our license, which would result in us being unable to develop, manufacture and sell pitolisant and would materially adversely affect our business.

The ongoing COVID-19 pandemic may result in disruptions to our commercialization, clinical trials, manufacturing and other business operations, which could have a material adverse effect on our business, financial condition, operating results, cash flows and prospects.

The outbreak of COVID-19, which has been declared a global pandemic by the World Health Organization, has spread across the globe and is impacting worldwide economic activity. A public health epidemic, including COVID-19, poses the risk that we or our employees, contractors, suppliers, distributors and other partners, as well as physicians treating narcolepsy patients, may be prevented from conducting business and patient-care activities for an indefinite period of time, including due to shutdowns and quarantines that may be requested or mandated by governmental authorities. Beginning in March 2020, we transitioned our field-based sales, market access, and medical employees to remote work and suspended work-related travel and in-person customer interactions with healthcare professionals and customers. Our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, remote working could increase our cyber security risk.

General protective measures put into place at various governmental levels, including quarantines, travel restrictions and business shutdowns, may also negatively affect our operations. The responses to the COVID-19 pandemic may have had an impact on demand for WAKIX as a result of 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 cancelled appointments and the reprioritization of healthcare resources toward treating COVID-19. In particular, we expect that our ability to convert prescriptions to revenue and the corresponding revenue growth rate in the fourth quarter of 2020 and possible future quarters will be adversely impacted by the ongoing COVID-19 pandemic. The COVID-19 pandemic has affected our ability to access HCPs, and has caused fewer patients visits to their HCP, resulting in fewer prescriptions being written. The COVID-19 pandemic is leading to high unemployment and corresponding loss of insurance, resulting in more eligible patients taking advantage of patient assistance and/or free good programs, which is impacting our ability to convert demand to revenue and the corresponding revenue growth rate in the fourth quarter of 2020 and possible future quarters will be adversely impacted by the ongoing COVID-19 pandemic.

The continued spread of COVID-19 and the measures taken by the governments of countries affected, particularly the United States and France, could also disrupt the supply chain and the manufacture or shipment of WAKIX and of drug substance and finished drug product. Any delays or interruptions in the manufacture and supply of WAKIX could result in delays for our planned clinical trials, impair our ability to meet demand for new WAKIX prescriptions and impede our clinical trial recruitment, testing, monitoring, data collection and analysis and other related activities.

Any of the foregoing factors could have a material adverse impact on our business, financial condition, operating results, cash flows and prospects. The extent to which COVID-19 impacts our operations and those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information which emerges concerning the severity of COVID-19 and the actions taken to contain the virus or treat its impact, among others. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, will determine the impact of the pandemic on our operations.

We may not be successful in our efforts to identify, in-license or acquire, discover, develop or commercialize additional product candidates, or identify other indications for pitolisant beyond EDS or cataplexy in adult patients with narcolepsy.

Although a substantial amount of our effort will focus on the commercialization of WAKIX for the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, we also may seek to identify, in-license or acquire, discover, develop and commercialize additional product candidates in the rare neurological disorders field, and to identify other indications for pitolisant beyond the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy. We cannot assure you that our efforts to do so will be successful. Even if we are successful at in-licensing or acquiring additional product candidates, their requisite development activities may require substantial resources, and we cannot assure you that these development activities will result in regulatory approvals. We also cannot assure you that our efforts to develop and commercialize pitolisant for other indications beyond the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy will be successful.

Our business, products or product pricing could be subject to negative publicity, which could have a material adverse effect on our reputation, business, financial position, results of operations, liquidity and cash flows.

In recent years, the pharmaceutical industry has been the subject of public complaints and significant publicity regarding the pricing of pharmaceutical products, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public has deemed excessive. We may experience downward pricing pressure on the price of WAKIX and any other future approved products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. Orphan drugs in particular have received recent negative publicity for the perceived high prices charged for them by their manufacturers, and as a result orphan drug developers such as us may be negatively impacted by such publicity and any U.S. or other government regulatory response. Due to these factors, we may suffer public criticism and negative publicity in media coverage, by industry trade associations and legislators.

Any of the events or developments described above could result in reputational harm and reduced market acceptance and demand for our products, could harm our ability to market our products in the future, could cause us to incur significant expense, could cause our senior management to be distracted from execution of our business strategy, and could have a material adverse effect on our business, reputation, financial condition, results of operations, liquidity, cash flows and/or share price.

Third-party relationships are important to our business. If we are unable to enter into and maintain strategic collaborations or if these relationships are not successful, our business could be adversely affected.

We have limited product development and distribution capabilities and we do not yet have any product manufacturing capabilities. In addition, we may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Relationships we enter into may pose a number of risks, including the following:

- current or future third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- third parties may not perform their obligations as expected;
- third parties may not pursue development and commercialization of any product candidates that we decide to develop as drugs and that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical study or trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- third parties may delay preclinical studies or clinical trials, provide insufficient funding for a preclinical study or clinical trial, stop a preclinical study or clinical trial or abandon one of our product candidates, repeat or conduct clinical studies or new clinical trials or require a new formulation of a product candidate for clinical testing;
- third parties could independently develop, or develop with other third parties, products that compete directly or indirectly with our products and product candidates if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our current or future collaborators as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our product candidates;
- third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, packaging, labeling, holding, distribution and/or marketing of a product candidate or product;
- third parties with marketing and distribution rights to pitolisant or any future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of pitolisant or any future product candidates, might lead to additional responsibilities for us with respect to pitolisant or any future product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- third parties may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- third parties may infringe the intellectual property rights of other third parties, which may expose us to litigation and potential liability;
- if one of our third parties is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- relationships may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our relationships do not result in the successful discovery, development and commercialization of products or if a third party terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under any third party agreements we enter into, our development of pitolisant or any future product candidates could be delayed and we may need additional resources. Additionally, if any third party terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into relationships or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected.

We expect to rely on third parties to conduct our clinical trials for pitolisant and any future product candidate that we decide to develop. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates on a timely basis or at all.

We will continue to rely upon third parties, including independent investigators, to conduct preclinical studies or clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and study or trial sites, which may result in delays to our development timelines and increased costs.

We will have to rely heavily on third parties over the course of our preclinical studies and clinical trials and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol and regulatory requirements. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with Good Clinical Practice ("GCP") requirements for clinical trials, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development.

Regulatory authorities enforce these GCP requirements through periodic inspections of study or trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these clinical trials or perform additional clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP or other applicable requirements. In addition, our clinical trials must be conducted with drug products produced under current Good Manufacturing Practices ("cGMP") requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these regulations, which would delay the regulatory approval or commercialization process. Moreover, our business may be implicated if any of these third parties violates federal or state laws or regulations including fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any parties conducting our future clinical trials, if any, generally will not be our employees and, except for remedies that may be available to us under our agreements with the third parties conducting such clinical trials, if any, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our

behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our current and future product candidates. As a result, our financial results and the commercial prospects for our current and future product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into contractual and other arrangements with alternative CROs or other third parties in a timely manner to meet projected clinical development deadlines or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially affect our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we experience delays in meeting or fail to meet the regulatory requirements for commercialization of our current or future potential product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We rely completely on third parties to manufacture and distribute our supply of WAKIX, including certain sole-source suppliers and manufacturers, and intend to rely on third parties to manufacture and distribute any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute commercial quantities of WAKIX. Our ability to commercially supply WAKIX depends, in part, on the ability of third-party manufacturers to supply and manufacture the raw materials, active pharmaceutical ingredient (“API”) and other important components related to the manufacture of WAKIX. We also rely on third parties to package the finished product. These third-party manufacturers have limited experience manufacturing the raw materials and API for WAKIX to be supplied to patients in the United States. Prior to the approval of WAKIX, we experienced minor issues related to product specifications and other minor delays in supply related to our third-party suppliers and manufacturers. While we continue to work with our third-party suppliers and manufacturers to optimize the manufacturing process for WAKIX and will work to optimize the manufacturing process for any future product candidates, we cannot guarantee that even minor changes in the process will result in products that are safe and, where applicable, effective. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to successfully commercialize WAKIX.

We rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. For example, we rely on Interor S.A., Corden Pharma Chenôve SAS and Patheon UK Limited to provide intermediate supply ingredients, API and finished products, respectively. Additionally, we rely on our suppliers and manufacturers to purchase materials from other third parties. Any of our existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole- source suppliers and manufacturers;
- supply us with product that fails to meet regulatory requirements;
- become unavailable through business interruption or financial insolvency;
- lose regulatory status as an approved source;
- be unable or unwilling to (i) honor current supply agreements or (ii) renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer technical processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA. Any need to find and qualify new suppliers or manufacturers could significantly delay production of WAKIX, adversely impact our ability to market WAKIX and adversely affect our business. There can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials beyond our currently forecasted needs. Any interruption in the supply of a drug substance or other material or in the manufacture of WAKIX could have a material adverse effect on our business, financial condition, operating results and prospects.

Additionally, although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMP for production of both drug substances and finished products. Facilities used by our contract suppliers and manufacturers to produce the drug substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. A number of our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of WAKIX is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize our product and we may be held liable for injuries sustained as a result. In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our product into the United States or other countries as a result of, among other things, regulatory agency approval requirements, taxes, tariffs, local import requirements such as import duties or inspections, incomplete or inaccurate import documentation or defective packaging.

Any of these factors could adversely impact our ability to effectively commercialize WAKIX.

Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in science in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.

Competition from other biotechnology and pharmaceutical companies is intense and is expected to increase. There may be a number of companies pursuing the development of pharmaceuticals in rare neurological disorders, our area of focus. These companies may be very large, and may have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors may enable them to develop, obtain regulatory approval for or market competing products more quickly or effectively, making it extremely difficult for us to capture a share of the market for our product. We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. Generic competition often results in decreases in the prices at which branded products can be sold. The commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. We also face competition from off-label uses of approved drugs. Additionally, the biotechnology and pharmaceutical industries are subject to rapid changes in science, and our competitors may develop and market products with improved therapeutic profiles relative to pitolisant or any future product candidates that would render pitolisant or any future product candidates noncompetitive.

We may need to increase the size and capabilities of our organization based on business need, and we may experience difficulties in managing our growth.

We commenced operations in 2017 and, as of September 30, 2020, had approximately 150 employees. As we advance the development of pitolisant in other indications and commercialize WAKIX as a treatment for EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, we must continue to grow the size of the organization. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- effectively managing our development efforts, including the clinical development and FDA or other regulatory authority review processes for pitolisant or any future product candidates;

- effectively managing any third-party service providers involved in the development and manufacture of pitolisant or any future product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and commercialize WAKIX or any future product candidates will depend, in part, on our ability to effectively manage any future growth. Our management will have to dedicate a significant amount of its attention to managing these growth activities. In addition, we expect to incur additional costs in hiring, training and retaining such additional personnel.

If we are not able to effectively expand our organization, we may not be able to successfully execute the tasks necessary to further develop and commercialize pitolisant or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our management and scientific teams. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity award grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by changes in the price of our common stock that are beyond our control, and may at any time be insufficient to retain employees who receive more lucrative offers from other companies. Any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified operations, finance and accounting, quality and compliance, scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. If we are unable to attract, retain and motivate qualified and experienced personnel, it could harm our business, results of operations and financial condition. Even if we are successful in attracting and retaining such personnel, competition for such employees may significantly increase our compensation costs and adversely affect our business, results of operations and financial condition.

The loss of the services of any of our executive officers, key employees or consultants could seriously harm our ability to successfully implement our business strategy. Replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may hire part-time employees or use consultants. As a result, certain of our employees, officers, directors or consultants may not devote all of their time to our business, and may from time to time serve as employees, officers, directors and consultants of other companies.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, the manufacturing facilities of our third-party contract manufacturers or our or their distribution networks, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, or interruptions in the commercialization of WAKIX or our business operations. Natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented

us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities, the manufacturing facilities of our third-party contract manufacturers or our or their distribution networks, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

We depend on our information technology systems, and any failure of these systems could harm our business. Any real or perceived security breaches, loss of data, and other disruptions or incidents could compromise the privacy, security, integrity or confidentiality of sensitive information related to our business or prevent us from accessing critical information and expose us to liability and reputational harm, which could adversely affect our business, results of operations and financial condition.

We collect and maintain data and information that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including systems infrastructure operated and maintained by our third party suppliers or providers. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems and facilities to prevent an information compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, denial-of-service attacks, cyber- attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization (including employees or contractors), lost or stolen devices, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through social engineering attacks, cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a real or perceived security breach affects our systems (or those of our third party providers or suppliers) or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of or other processing of personally identifiable information or clinical trial data, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Clinical Health Act of 2009 (“HITECH”), and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss, negative publicity, harm to our reputation, governmental investigation and/or enforcement actions, claims

or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we begin to operate in foreign jurisdictions.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse laws, data privacy and security laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use or misrepresentation of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval process of the FDA is costly, lengthy and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for pitolisant in other potential indications for which we may seek to develop pitolisant, our business will be substantially harmed.

Although the commercialization of WAKIX is our primary focus, as part of our longer-term growth strategy, we plan to evaluate pitolisant in other indications and develop other product candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, pricing and reimbursement marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory agencies in the United States. Although we have obtained regulatory approval for WAKIX in the United States for the treatment of EDS or cataplexy in adult patients with narcolepsy, it is possible that we may not obtain regulatory approval for pitolisant for other indications, or for any other product candidates we may seek to develop in the future. We received a Complete Response Letter (“CRL”) for pitolisant for the treatment of cataplexy in adult patients with narcolepsy, and therefore the FDA did not approve WAKIX for this indication during the initial NDA review. Subsequently, in June 2020, we received a general advice letter from the FDA stating that the FDA had re-analyzed data from the HARMONY 1 trial that we submitted in the NDA in support of the adult cataplexy indication for WAKIX. As a result, the FDA recommended we submit a complete response resubmission in pursuit of the adult cataplexy indication for WAKIX. Following such resubmission, we received acknowledgement from the FDA that it considers the resubmission to be a complete Class 1 response to its August 14, 2019 action letter, and the user fee goal date, or decision date, was October 13, 2020. On October 13, 2020 we received regulatory approval for WAKIX for the treatment of cataplexy in adult patients with narcolepsy. Nevertheless, obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process.

The FDA can delay, limit or deny approval of a drug candidate for many reasons or require us to conduct additional preclinical or clinical testing, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective, or the clinical and other benefits may be deemed to not outweigh the candidate's risks;
- the FDA might not approve our trial design and analysis plan;
- the FDA may not find the data from nonclinical and clinical studies and trials sufficient or may disagree with our interpretation of data from nonclinical or clinical studies;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing the active ingredient in our product candidates;
- clinical inspection(s) by the FDA or other regulatory authorities may result in unacceptable findings that could negatively impact approval of pitolisant;
- the FDA might not accept or deem acceptable a third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

Prior to obtaining approval to commercialize a drug candidate in the United States, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such drug candidates are safe and effective for their intended uses. The number of nonclinical and clinical studies and trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. If pitolisant fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval for other indications, our business and results of operations will be materially and adversely harmed. Additionally, if the FDA requires that we conduct additional clinical trials, places limitations on pitolisant in our label, delays approval to market pitolisant or limits the use of pitolisant, our business and results of operations may be harmed.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we fail to obtain and sustain an adequate level of coverage and reimbursement for WAKIX and other product candidates by third-party payors, sales would be adversely affected.

Successful sales of WAKIX and any other product candidates that may receive regulatory approval depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. Commercial third-party payors, such as private health insurers and health maintenance organizations, also decide which medications they will pay for and establish reimbursement levels, though commercial third-party payors often follow CMS' reimbursement determinations. The availability of

coverage and the extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of WAKIX or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for WAKIX and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Obtaining coverage and reimbursement approval for a product from a government or other third- party payor can be an expensive and time-consuming process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. The industry competition to be included in third-party payors' drug formularies, or lists of medications for which third- party payors provide coverage and reimbursement, often leads to downward pricing pressures on pharmaceutical products. In addition, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average manufacture price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level ofreimbursement.

In addition, there may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses.

Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

While we have obtained coverage for WAKIX from certain third-party payors, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use WAKIX unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of WAKIX. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We may suffer loss of corporate reputation due to industry-wide legislative or public scrutiny of our pricing decisions and practices within an increasingly price-sensitive environment.

Despite obtaining formulary approval from certain third-party payors, sometimes with prior authorization or other formulary restrictions and requirements, including documented failure or inadequate response to alternative treatments, we expect to experience pricing pressures in connection with the sale of WAKIX due to the trend toward cost containment, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are questioning the coverage of, and challenging the prices charged for medical products and services, and many third- party payors limit coverage of, or reimbursement for, newly approved health care products. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for WAKIX.

These cost-control initiatives could decrease the price we have established for WAKIX, which could result in product revenues being lower than anticipated. The pricing, coverage and reimbursement of WAKIX must be adequate to support a commercial infrastructure. If the price for WAKIX decreases or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, our revenue, gross margins and prospects for profitability will suffer.

While we have not taken any steps to attain regulatory or patent approvals in any specific markets outside of the United States, we plan to explore obtaining additional licensing rights from Bioprojet to expand into international markets with WAKIX**.** Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries will likely put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for WAKIX. Accordingly, in markets outside the United States, the reimbursement for WAKIX may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

WAKIX has been approved by the FDA for the treatment of EDS in adult patients with narcolepsy, and cataplexy in adult patients with narcolepsy. Regulatory approval is limited by the FDA to the specific indication for which approval has been granted and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing pitolisant for other indications. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of pitolisant for unapproved or "off-label" uses, resulting in damage to our reputation and business.

While we received approval for the indications of the treatment of EDS in adult patients with narcolepsy and cataplexy in adult patients with narcolepsy, WAKIX is not indicated to treat any other conditions. We are prohibited from promoting WAKIX for any other indication unless we are granted FDA approval for such indication. The FDA strictly regulates the promotional claims that may be made about prescription products, and WAKIX may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians

in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or pharmaceutical companies on off-label use. If the FDA determines that our promotional activities constitute promotion of an off-label use, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

WAKIX or any of our future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, reduce the commercial attractiveness of a prescribing label or result in significant negative consequences following regulatory approval, if approved.

Clinical trials of WAKIX or other product candidates we may develop could reveal a high and unacceptable incidence and severity of undesirable side effects. Undesirable side effects could adversely affect patient enrollment in clinical studies, cause us or regulatory authorities to interrupt, delay or halt clinical studies or result in the delay, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities. Undesirable or adverse side effects also could result in regulatory authorities mandating a more restrictive prescribing label for the product, which, in turn, could limit the market acceptance of the product even if approved for marketing and commercialization.

Drug-related side effects could result in potential product liability claims. We believe our product liability insurance coverage is sufficient in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or maintain coverage at all to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations, business and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, significant negative media attention, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our current product candidate or any future product candidate, product recalls, restrictions on labeling, marketing or promotion, decreased demand for our product candidates, if approved for marketing, and loss of revenue.

Additionally, if we or others later identify undesirable side effects caused by WAKIX, either in the post-marketing setting or in clinical trials in other potential indications for which we develop pitolisant, or in clinical trials for other product candidates, a number of potentially significant negative consequences could result, including but not limited to:

- the delay, prevention or withdrawal of approvals by regulatory authorities;
- the requirement of additional warnings on the prescribing label;
- the requirement of a Risk Evaluation and Mitigation Strategy ("REMS") plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- designation as a controlled substance by the U.S. Drug Enforcement Administration ("DEA");
- litigation and the potential to be held liable for harm caused to patients; and
- an adverse effect on our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of pitolisant and could significantly harm our business, results of operations, financial condition and prospects.

We have never commercialized a product candidate prior to WAKIX and we may lack the necessary expertise, personnel and resources to successfully commercialize WAKIX or any other potential product candidates that receive regulatory approval on our own or together with collaborators.

WAKIX is our first commercialized product. Prior to this, our operations had been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no in-house manufacturing, distribution or supply capabilities. To achieve commercial success of WAKIX or any other product candidate, if approved, we will have to develop our own manufacturing, distribution and supply capabilities or outsource these activities to a third party.

We are early in our commercialization efforts. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications (“ANDAs”) in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”), provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity (“NCE”). Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

While we have received five years of NCE exclusivity for WAKIX, manufacturers may seek to launch generic products following the expiration of the applicable exclusivity period we obtain, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could materially and adversely affect our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards ("IRBs") or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects or patients required for clinical trials of pitolisant in additional indications or any other product candidate may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of pitolisant or any other product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs of the institutions in which clinical trials are being conducted or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive results from our ongoing clinical trials of pitolisant for the treatment of narcolepsy, or any other clinical trial or preclinical studies in animals that we conduct, could mandate repeated or additional clinical trials and could result in changes to or delays in clinical trials in other indications. We do not know whether any clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market pitolisant for our initial or potential additional indications, or any other product candidate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for pitolisant for initial or potential additional indications, or any other product candidate, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of pitolisant for potential additional indications or any other product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market pitolisant or any other product candidate would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of pitolisant or any other product candidate.

In addition, prior to our acquisition of the rights to pitolisant, we had no involvement with or control over the nonclinical or clinical development of pitolisant. Additionally, pursuant to our collaboration agreement with Bioprojet, we will rely on data generated by Bioprojet in connection with seeking regulatory approval of pitolisant in the territories in which we have rights to develop and commercialize pitolisant. We are dependent on Bioprojet having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to pitolisant, having correctly collected and interpreted the data from these trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to predecessors could result in increased costs and delays in the development of pitolisant for additional indications, which could adversely affect our ability to generate any future revenue from sales of pitolisant, if approved for additional indications.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, "topline" or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available topline data, and the results and related findings and conclusions are subject to change following completion of the study or a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, "topline" or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. "Topline" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, "topline" data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, "topline" or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Furthermore, any negative results or new safety signals we or third parties may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in our clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical

trials. In addition, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop pitolisant or any future product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Even though the FDA granted orphan drug designation to pitolisant for the treatment of narcolepsy, we may not be able to obtain or maintain orphan drug marketing exclusivity for this product candidate or any other product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Pitolisant was granted orphan drug designation for the treatment of narcolepsy in 2010. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. Under the FDA's regulations, the FDA will deny orphan drug exclusivity to a designated drug upon approval if the FDA has already approved another drug with the same active ingredient for the same indication, unless the drug is demonstrated to be clinically superior to the previously approved drug. The applicable exclusivity period is seven years in the United States. Orphan drug exclusivity in the United States may be unavailable where the indication for which the product candidate is approved is broader than the orphan-designated indication, or is otherwise different from the orphan-designated indication. For example, the FDA granted orphan drug designation for pitolisant for the treatment of narcolepsy. Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the candidate from competition. WAKIX may face additional competition because different drugs with a different active moiety can still be approved for the same condition. Even after an approved drug is granted orphan exclusivity, exclusivity may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition following approval. In addition, the FDA can subsequently approve products with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 ("FDARA"). FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease or condition in order to receive orphan drug exclusivity. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We are subject to ongoing regulatory obligations and continued regulatory review with respect to WAKIX, which will result in significant additional expense. Additionally, WAKIX could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with WAKIX.

WAKIX is subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, distribution, import, export, record keeping and submission of safety and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Our regulatory approval for WAKIX for the treatment of EDS or cataplexy in adult patients with narcolepsy, and any other regulatory approvals we may receive for pitolisant or any future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, which must comply with applicable GCP regulations. We could also be asked to conduct post marketing clinical studies to verify the safety and efficacy of future product candidates in general or in specific patient subsets. For example, as a part of the regulatory approval for WAKIX for the treatment of EDS in adult patients with narcolepsy, we are required to conduct post-marketing studies in women exposed to pitolisant in pregnancy, including a registry-based observational cohort study to assess maternal, fetal, and infant outcomes of women exposed to pitolisant during pregnancy, and another study of a different design such as a case control study or a retrospective cohort study using electronic medical record data, and a lactation study.

We will also be required to report certain adverse events and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for WAKIX. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote WAKIX for indications or uses for which it does not have FDA approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process.

If a regulatory agency discovers previously unknown problems with WAKIX, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on the product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning or untitled letters;
- impose civil or criminal penalties, including product seizures and injunctions;
- limit or suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities, on the manufacturing of our products, or on the labeling or marketing of our products; or
- seize or detain products or require a product recall or withdrawal of the products from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from WAKIX or future product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from the sale of WAKIX or future product candidates, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

The regulatory requirements and policies may change, and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, may face government enforcement action and our business will suffer.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, certain policies of the Trump administration may affect our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these

executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. The laws that affect our current and future operations include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for, or to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item, or service for which payment may be made, in whole or in part, under any U.S. federal healthcare programs, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, such as the False Claims Act ("FCA"), which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, and prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended HITECH, and its implementing regulations, which imposes privacy, security and breach reporting obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information upon covered entities subject to the rule, such as health

plans, healthcare clearinghouses and healthcare providers and their respective business associates and independent contractors that perform certain services for them that involve the use or disclosure of individually identifiable health information on their behalf. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- state law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and may be broader in scope than their federal equivalents;
- federal transparency requirements detailing interactions with and payments to healthcare providers, such as the federal reporting requirements under the Physician Payments Sunshine Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the HHS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals starting January 1, 2022, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Failure to submit required information may result in civil monetary penalties;
- state laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers and other potential referral sources, state laws that require drug manufacturers to file reports relating to pricing information and marketing expenditures, state and local laws requiring the registration of pharmaceutical sales representatives; and other state laws and regulations that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar healthcare and data protection laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation ("GDPR"). Ensuring that our business operations and current and future arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including, without limitation, our patient support and financial assistance programs, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil, administrative and criminal penalties, damages, fines, the curtailment or restructuring of our operations, contractual damages, disgorgement, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve

allegations of non-compliance with these laws, the exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to market pitolisant, if approved, and adversely impact our financial results. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources.

Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the applicable regulatory agencies or the courts, and their provisions are open to a variety of interpretations.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Clinical practice guidelines and recommendations published by various organizations could have significant influence on the use of WAKIX.

Professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to the healthcare and patient communities. The recommendations of these groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of WAKIX or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of WAKIX.

Product candidates we develop in the future may be classified as controlled substances, the making, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Product candidates we develop in the future may be classified as controlled substances, which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the federal Controlled Substances Act of 1970 (the "CSA") and regulations of the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our products or product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates, and, in the case of our approved products, the ability to produce and distribute our products in the volume needed to meet commercial demand.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our approved products or product candidates that are classified as controlled substances.

Enacted and future healthcare legislative changes may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States, the European Union and other some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to the pharmaceutical industry and our potential product candidates are the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program for branded and generic drugs;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing challenges in the Fifth Circuit Court and the U.S. Supreme Court, the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation and regulations designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review 2020 relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in April of 2018, CMS published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, Congress has indicated that it will continue to seek new legislative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. It would require HHS to directly negotiate drug prices with manufacturers. It is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business.

Additionally, in 2019, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. HHS has also begun implementation of the Trump administration Blueprint, soliciting feedback on some of these measures and, immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2029. The Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), which was signed into law in March 2020, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one additional year, through 2030. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review 2020 relationship between pricing and manufacturer patient programs. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates, once approved, or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect to participate in and have certain price reporting obligations to the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data we would have to report on a monthly and quarterly basis to the CMS, the federal agency that administers the Medicaid Drug Rebate Program. These data include, among other things, the average manufacturer price ("AMP") and, in the case of innovator products, the best price ("BP") for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly and/or quarterly AMP and BP data on a timely basis could result in a civil monetary penalty for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA or other legislation or regulation could affect our 340B ceiling price calculations and negatively impact our results of operations commercializing pitolisant. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have our products that we successfully commercialize paid for with federal funds under the Medicaid program and purchased by certain federal agencies and grantees, we also would have to participate in the U.S. Department of Veterans Affairs ("VA"), Federal Supply Schedule ("FSS") pricing program. As part of this program, we would be obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price ("FCP") to four federal agencies (VA, U.S. Department of Defense ("DOD"), Public Health Service, and U.S. Coast Guard).

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and antimony laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may have direct or indirect interactions with officials and

employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, which could prevent new products and services from being developed or commercialized in a timely manner, which could negatively affect our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other governmental employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which harm our business. Similarly, a prolonged government shutdown could prevent the timely review of any of our patent applications by the U.S. Patent and Trademark Office (“USPTO”), which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA reviews proposed product names, considering both the potential for the name to lead to medical errors due to confusion with other product names and whether the proposed name is overly fanciful, misleadingly implies unique effectiveness or composition, or contributes to overstatement of product efficacy, minimization of risk, broadening of product indications or unsubstantiated superiority. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, on a combination of patents, trademarks and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future product candidates. Our success depends in large part on our licensor’s ability to obtain and maintain patent protection in the United States with respect to WAKIX and our ability to obtain and maintain patent protection in the United States and any other relevant foreign jurisdictions with respect to any future product candidates that we develop. We seek to ensure that our current and future licensors obtain appropriate patent protection to all product candidates that we license from them. The patent prosecution process is expensive and time- consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Our patent portfolio comprises four U.S. patents exclusively licensed to us from Bioprojet. One U.S. patent, No. 8,207,197 has claims directed to a polymorph, i.e. a specific crystalline form, of pitolisant and, methods for preparing that polymorph of pitolisant, which is expected to expire in February 2029 without taking into consideration any possible patent term extension. A second U.S. patent, No. 8,486,497, has claims directed to methods of treating excessive daytime sleepiness by administering pitolisant, which is expected to expire in September 2029 without taking into consideration any possible patent term extension. With all applicable patent term adjustments available and granted to us, the term of the last-to-expire pitolisant-related patent in our portfolio extends to September 2029.

The patents that we in-license now or the patents and patent applications that we own or in-license in the future may not have patentable claims that protect our current and future product candidates in the relevant jurisdictions where we intend to commercialize such products. There is no assurance that we and our licensor are aware of all potentially relevant prior art relating to future patent applications. As such, the patent examiner may find prior art that can prevent a patent from issuing from a pending patent application. During the patent examination process, we or our licensor may be required to narrow the pending claims to overcome prior art, a process that may limit the scope of patent protection. Even if patents do successfully issue based on our future patent applications, and even if the issued patents cover our current and future product candidates, including their compositions formulation, method of manufacture, and method of use, third parties may challenge our issued patents' validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us in the future could deprive us of rights necessary for the successful commercialization of any of our current or future product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we may own or in-license in the future with respect to our current and future product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates, it could dissuade other companies from collaborating with us to develop future product candidates, and threaten our ability to commercialize our current and future product candidates. Notably, pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could have an adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and challenged at the USPTO and may also affect patent litigation. The USPTO has developed and continues to develop new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it remains unclear what impact the Leahy-Smith Act, subsequent rulemaking, and judicial interpretation of the Leahy-Smith Act and regulations will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition. Moreover, future changes to the patent laws of the United States and foreign jurisdictions may adversely affect the term, scope, validity and enforceability of our or our licensor's patent rights. For example, a new bill (Terminating the Extension of Rights Misappropriated Act, or TERM Act, H.R. 3199) percolating through the United States Congress aims to reduce the term of certain drug patents in order to ease generic entry and increase competition.

The inventorship and ownership rights for patents that we in-license or may own or in-license in the future may be challenged by third parties. Such challenges could result in loss of exclusive rights to such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or require us to obtain a license from such third parties on commercially reasonable terms to secure exclusive rights. If any such challenges to inventorship or ownership were asserted, there is no assurance that a court would find in our favor or that, if we choose to seek a license, such license would be available to us on acceptable terms or at all.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in pre- and post-issuance opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications, whether owned or in-licensed now or in the future, is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our licensed patents may be challenged in the courts or patent offices in the United States. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after the filing of the earliest non-provisional application to which the patent claims priority. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We may be required to disclaim a portion of patent term in order to overcome double patenting rejections from the patent office, thus potentially shortening our exclusivity period. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future product candidates.

We have licensed certain intellectual property rights covering pitolisant from Bioprojet, and we may license intellectual property rights from others in the future. If, for any reason, our license agreement with Bioprojet or any future licensor is terminated or we otherwise lose the rights associated with a license, it could adversely affect our business. Our license agreement with Bioprojet imposes, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term for our current and future product candidates, our business may be harmed.

Our commercial success will largely depend on our licensor’s ability to obtain and maintain patent and other intellectual property in the United States for pitolisant, and our target indications, and our ability to maintain obtain and maintain patent and other intellectual property in the United States for any product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States.

Depending upon the timing, duration and specifics of FDA marketing approval of our current and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to

only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request.

If we or our licensor are unable to extend the expiration date of our or their existing patents or obtain new patents with longer expiry dates, as applicable, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our current and future product candidates can be challenged by third parties.

One or more third parties may challenge the current patents, or future patents within our portfolio, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an ANDA for a generic drug containing pitolisant, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or future patents within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing, for example, pitolisant, and relies in whole or in part on studies conducted by or for us.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our current and future product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain patents and patent applications, whether owned or in-licensed now or in the future, covering any of our current or future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

We may need to acquire or license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our current and future product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our current and future product candidates, if approved, would likely be delayed.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our current or future product candidates.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may in the future be developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.

Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our current and future product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our current and future product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or

whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our current and future product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current and future product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current and future product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current product candidate in any jurisdiction.

It is possible that we and our current and future licensors will fail to identify patentable aspects of research and development output before it is too late to obtain patent protection. The patent applications that we may own or in-license in the future may fail to result in issued patents with claims that cover our current and future product candidates. We and our current and future licensors may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of the patent applications, which may result in such patents being narrowed, invalidated or held unenforceable.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively affect our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively affect our ability to develop and market our products.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate the patents of our licensor or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that an asserted patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the asserted patent does not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of asserted patents at risk of being invalidated or interpreted narrowly and could put a related patent application at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we may license in the future, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our in-licensed patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued numerous precedential opinions in recent years narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, non-transferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees’ former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Any trademarks we have obtained or may obtain may be infringed or be successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our current and future product candidates that are approved for marketing from the products of our competitors. For example, we are marketing pitolisant for the treatment of EDS or cataplexy in adult patients with narcolepsy under the brand name WAKIX, which we have licensed from Bioprojet. We may design or create new trademarks and apply to register them, our trademark applications may not be approved in the United States or any relevant foreign jurisdiction. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Being a Public Company

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (the “Sarbanes Oxley Act”), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors’ and officers’ liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act (“Section 404”), to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the fiscal year beginning January 1, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal controls procedures on a quarterly basis.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and finance staff and consultants with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal controls over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal controls over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline. 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 are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that have not made this election.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three fiscal years; or (iv) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC.

Our management team has limited experience managing a public company.

Our chief executive officer does not have experience managing a public company, interacting with public company investors or complying with the increasingly complex laws pertaining to public companies. Our management team, as a whole, may not successfully or efficiently manage the transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management, particularly from our chief executive officer, and could divert their attention away from the day-to-day management of our business, which could adversely affect our revenue, business, results of operations and financial condition.

Risks Related to Ownership of our Common Stock

An active trading market for our common stock may not be maintained.

Our common stock only recently began trading on the Nasdaq Global Market, and we can provide no assurance that we will be able to maintain an active trading market on The Nasdaq Global Market or any other exchange in the future. If an active trading market for our common stock is not maintained, or if we fail to satisfy the continued listing standards of The Nasdaq Global Market for any reason and our common stock is delisted, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our directors, officers and principal stockholders beneficially own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2020, our directors, officers, five percent or greater stockholders, and their respective affiliates beneficially owned in the aggregate approximately 80% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, and approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Certain holders of our common stock are entitled to rights with respect to registration of such shares under the Securities Act pursuant to a registration rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if our operating results do not meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting pitolisant;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the achievement and timing of milestone payments under our existing collaboration and license agreements; and
- the level of underlying demand for WAKIX and customers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

In the future, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, consultants and directors pursuant to our equity incentive plans. If we sell common stock, convertible securities or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

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, we are party to a Credit Agreement with OrbiMed that contains negative covenants that limit our ability to pay dividends.

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we are subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law (the “DGCL”). Under Section 203 of the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our current or former directors, officers, employees or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our stockholders are deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

Use of Proceeds from our Initial Public Offering of Common Stock

On August 21, 2020, we completed the IPO of our common stock, in which we issued and sold 6,151,162 shares, including 802,325 shares pursuant to the underwriters' over-allotment option at a price of $24.00 per share for an aggregate price of approximately $147.6 million. The shares began trading on the Nasdaq Global Market on August 19, 2020. The offer and sale of the shares in our IPO was registered under the

Securities Act pursuant to a registration statement on Form S-1 (File No. 333-240122), which was declared effective by the SEC on August 18, 2020 (the "Registration Statement"). The offering commenced on August 6, 2020 and terminated after the sale of all securities registered pursuant to the Registration Statement. Goldman Sachs & Co. LLC., Jefferies LLC and Piper Sandler & Co. acted as managing underwriters for the offering. We raised approximately $135.4 million, after deducting underwriting discounts and commissions and offering expenses of approximately $12.2 million. None of these expenses consisted of direct or indirect payments made by us to (i) our directors, officers or their associates, (ii) persons owning 10% or more of our common stock or (iii) to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus. Net proceeds from our IPO have been invested in short-term, interest-bearing, investment grade securities.

Unregistered Sales of Equity Securities

On August 31, 2020, pursuant to Article IV, Section B, Subsection 5.2 of our Third Amended and Restated Certificate of Incorporation, as amended, we delivered to each holder of our previously outstanding Series A preferred stock (the "Series A Preferred"), Series B preferred stock (the "Series B Preferred") and Series C preferred stock (the "Series C Preferred" and, together with the Series A Preferred and the Series B Preferred, the "Preferred Stock") a notice indicating the number of shares of our common stock each such holder held following the conversion of the Preferred Stock into our common stock and the payment of the cumulative accrued dividend in shares of our common stock.

As previously reported, from September 22, 2017 through January 8, 2018, we issued and sold an aggregate of 34,692,635 shares of Series A Preferred at a purchase price of $8.22 per share for aggregate consideration of approximately $285.0 million. On January 8, 2018, we issued and sold an aggregate of 973,828 shares of Series B Preferred at a purchase price of $10.27 per share for aggregate consideration of approximately $10.0 million. On August 9, 2019, we issued and sold an aggregate of 3,105,320 shares of Series C Preferred at a purchase price of $16.10 per share, for aggregate consideration of approximately $50.0 million. All the Preferred Stock share numbers and prices disclosed above reflect our 1-for-8.215 reverse stock split, which was effected on August 11, 2020.

The Preferred Stock was issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

In connection with the IPO of our common stock, all of our outstanding shares of Preferred Stock were converted into shares of our common stock. In addition, we paid out a cumulative accrued dividend to holders of the Preferred Stock in shares of our common stock. Collectively, holders of the previously outstanding Preferred Stock received a total of 42,926,630 shares of our unregistered common stock, resulting in a total of 56,883,640 shares of our common stock outstanding following the IPO. All fractional shares were paid in cash. Substantially all shares of our common stock issued to holders of Preferred Stock are subject to a lock-up agreement that expires 180 days from August 18, 2020, the date the IPO was priced.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description	Incorporation by Reference			
		Form or Schedule	Exhibit Number	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of Harmony Biosciences Holdings, Inc.	8-K	3.1	August 21, 2020	001-39450
3.2	Amended and Restated Bylaws of Harmony Biosciences Holdings, Inc.	8-K	3.2	August 21, 2020	001-39450
4.1	Form of common stock certificate of the Registrant.	S-1	4.1	August 6, 2020	333-240122
10.1†	Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan	S-8	10.2	August 21, 2020	333-248243
10.2†	Form of Option Agreement under Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan.	S-8	10.3	August 21, 2020	333-248243
10.3†	Form of Restricted Stock Unit Agreement under Harmony Biosciences Holdings, Inc. 2020 Incentive Award Plan.	S-1	10.6	August 11, 2020	333-240122
10.4†	Harmony Biosciences Holdings, Inc. 2020 Employee Stock Purchase Plan.	S-1	10.7	August 11, 2020	333-240122
10.5†	Amended and Restated Employment Agreement, dated August 11, 2020, by and between Harmony Biosciences, LLC and John C. Jacobs.	S-1	10.8	August 11, 2020	333-240122
10.6	Form of Indemnification Agreement between Harmony Biosciences, LLC and each director and executive officer.	S-1	10.12	August 11, 2020	333-240122
10.7†	Harmony Biosciences, LLC Separation Plan.	S-1	10.13	August 11, 2020	333-240122
10.8†	Harmony Biosciences Holdings, Inc. Amended and Restated 2017 Equity Incentive Plan.	S-1	10.3	August 11, 2020	333-240122
10.9*†	Harmony Biosciences Holdings, Inc. Non-Employee Director Compensation Program.				
31.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1‡	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2‡	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				

** Filed herewith.*
‡ *Furnished herewith.*
† *Indicates a management contract or compensatory plan or arrangement.*

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 12, 2020

By: /s/ Susan L. Drexler
Name: Susan L. Drexler
Title: Chief Financial Officer (principal financial officer)
Date: November 12, 2020

EXHIBIT 10.9

HARMONY BIOSCIENCES HOLDINGS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Eligible Directors (as defined below) on the board of directors (the "***Board***") of Harmony Biosciences Holdings, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically as set forth herein and without further action of the Board, to each member of the Board who is not an employee of the Company or any of its parents, affiliates or subsidiaries, and who is determined by the Board to be eligible to receive compensation under this Program (each, an "***Eligible Director***"), who may be eligible to receive such cash or equity compensation, unless such Eligible Director declines the receipt of such cash or equity compensation by written notice to the Company.

This Program shall become effective upon the closing of the initial public offering of the Company's common stock (the "***Effective Date***") and shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. No Eligible Director shall have any rights hereunder, except with respect to equity awards granted pursuant to Section 2 of this Program.

1. Cash Compensation.

a. Annual Retainers. Each Eligible Director shall be eligible to receive an annual cash retainer of $45,000 for service on the Board.

b. Additional Annual Retainers. An Eligible Director shall be eligible to receive the following additional annual retainers, as applicable:

(i) Chairman of the Board. An Eligible Director serving as Non-Executive Chairman of the Board shall be eligible to receive an additional annual retainer of $40,000 for such service.

(ii) Audit Committee. An Eligible Director serving as Chairperson of the Audit Committee shall be eligible to receive an additional annual retainer of $20,000 for such service. An Eligible Director serving as a member of the Audit Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of $10,000 for such service.

(iii) Compensation Committee. An Eligible Director serving as Chairperson of the Compensation Committee shall be eligible to receive an additional annual retainer of $15,000 for such service. An Eligible Director serving as a member of the Compensation Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of $8,000 for such service.

(iv) Nominating and Corporate Governance Committee. An Eligible Director serving as Chairperson of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of $10,000 for such service. An Eligible Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of $5,000 for such service.

c. Payment of Retainers. The annual cash retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than 30 days following the end of each calendar quarter. In the event an Eligible Director does not serve as a director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Eligible Director shall be prorated for the portion of such calendar quarter actually served as a director, or in such position, as applicable.

2. Equity Compensation.

a. General. Eligible Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2020 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (such plan, as may be amended from time to time, the "***Equity Plan***") and may be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms approved by the Board prior to or in connection with such grants. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of equity awards hereby are subject in all respects to the terms of the Equity Plan. Capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the Equity Plan.

b. Initial Awards.

i. Each Eligible Director who is initially elected or appointed to serve on the Board after the Effective Date automatically shall be granted an Option with a value as set forth below (the "***Initial Equity Award***"):

1. An Eligible Director serving as Chairperson of the Audit Committee: $230,000.

2. An Eligible Director serving as Chairperson of the Compensation Committee: $175,000.

3. An Eligible Director (other than a Chairperson of the Audit Committee, Chairperson of the Compensation Committee or the Non-Executive Chairman of the Board): $125,000.

ii. The Initial Equity Award shall be granted on the date on which such Eligible Director is appointed or elected to serve on the Board, and shall vest and become exercisable as to 1/36th of the Shares underlying the Option on each monthly anniversary of the grant date, subject to such Eligible Director's continued service through the applicable vesting date, such that the Option is fully vested and exercisable on the third anniversary of the grant date, subject to such Eligible Director's continued service through the applicable vesting date.

c. Annual Awards.

i. An Eligible Director who is serving on the Board as of the date of the annual meeting of the Company's stockholders (the "***Annual Meeting***") each calendar year beginning with calendar year 2021 shall be granted an Option with a value as set forth below (an "***Annual Award***" and together with the Initial Equity Award, the "***Director Equity Awards***"):

1. An Eligible Director serving as Chairperson of the Audit Committee: $230,000.

2. An Eligible Director serving as Chairperson of the Compensation Committee: $175,000.

3. An Eligible Director (other than a Chairperson of the Audit Committee, Chairperson of the Compensation Committee or the Non-Executive Chairman of the Board): $125,000.

ii. Each Annual Award shall vest and become exercisable in full on the earlier to occur of (i) the one-year anniversary of the applicable grant date and (ii) the date of the next Annual Meeting following the grant date, subject to continued service through the applicable vesting date.

d. Accelerated Vesting Events. Notwithstanding the foregoing, an Eligible Director's Director Equity Award(s) shall vest and become exercisable in full immediately prior to the occurrence of a Change in Control to the extent outstanding at such time.

e. Provisions Applicable to Awards. With respect to any Award granted under this Program:

i. The exercise price per Share with respect to an Option shall be equal to the Fair Market Value of a Share on the applicable grant date.

ii. An Option shall have a maximum term of ten years from the applicable grant date.

iii. The number of Shares subject to an Option shall be determined by dividing the value of the Option by the per share Black-Scholes valuation as of the applicable grant date, utilizing the same assumptions that the Company uses in preparation of its financial statements.

3. Compensation Limits. Notwithstanding anything to the contrary in this Program, all compensation payable under this Program will be subject to any limits on the maximum amount of non-employee Director compensation set forth in the Equity Plan, as in effect from time to time.

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Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John C. Jacobs, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [Reserved];

   (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 12, 2020

By: /s/ John C. Jacobs

John C. Jacobs

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Susan L. Drexler, 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)) 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) [Reserved];

   (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 12, 2020

By: /s/ Susan L. Drexler
Susan L. Drexler
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 12, 2020

By: /s/ John C. Jacobs

John C. Jacobs

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Harmony Biosciences Holdings, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 12, 2020

By: /s/ Susan L. Drexler

Susan L. Drexler

Chief Financial Officer
(*Principal Financial and Accounting Officer*)