UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-43422

Apnimed, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-1910611**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
39 John F. Kennedy Street, 4th Floor Cambridge, MA	**02138**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 500-8880

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 per share	APMD	Nasdaq Global Select Market

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

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

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

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

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

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

As of November 10, 2026, the registrant had 41,630,779 shares of common stock, $0.00001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER MATTERS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements about us and our industry. 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 are forward-looking statements, including statements regarding the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, AD109, with a proposed proprietary name Oxnimbi™ (aroxybutynin and atomoxetine) tablets, for oral use ("Oxnimbi") or any future product candidates; our planned commercialization activities, and our ability to successfully commercialize Oxnimbi, if approved; the effects of competition with respect to Oxnimbi or any future product candidates; the rate and degree of market acceptance, as well as the pricing and reimbursement of Oxnimbi, if approved; the scope, progress, results and costs of developing Oxnimbi or any future product candidates and conducting nonclinical studies and clinical trials; our ability to maintain relationships with collaborators and licensors and identify and enter into future license agreements and collaborations; our ability to maintain and enforce our intellectual property rights; existing regulations and regulatory developments in the United States and other jurisdictions; our ability to attract and retain key personnel and to identify, hire and retain additional qualified personnel; our ability to attract additional collaborators with development, regulatory and commercialization expertise; general economic, industry and market conditions; our estimates regarding our capital requirements and needs for additional financing and our ability to obtain additional funding; and our anticipated cash runway, financial performance and estimates of expenses. 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. In this Quarterly Report, we refer to AD109 by its proposed future brand name, Oxnimbi. This brand name was conditionally approved by the FDA in May 2025, which was reconfirmed in June 2026, and is pending approval of the New Drug Application ("NDA") in its totality.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions.

We have based these forward-looking statements largely on our current expectations and estimates about future events and financial and other 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 and are subject to a number of risks, uncertainties and assumptions described under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those estimated in the forward-looking statements. 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. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

In addition, statements that "we believe" and similarly qualified statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon them.

This Quarterly Report contains references to trademarks belonging to us and other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report, including logos, artwork and other visual displays, generally appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

This Quarterly Report may include industry and market data, which we may obtain from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled "Risk Factors" in this Quarterly Report. These risks include, among others, the following:

- We are a late-stage clinical pharmaceutical company and have incurred significant operating losses since our inception and we expect to incur significant operating losses for the foreseeable future. We may never become profitable and, if profitability is ever achieved, we may not be able to sustain it.
- Our existing and any future indebtedness could adversely affect our ability to operate our business.
- We will require substantial additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business depends on the success of our sole clinical product candidate, Oxnimbi, which has completed Phase 3 clinical trials. If we are unable to obtain regulatory approval for or successfully commercialize Oxnimbi, or are significantly delayed in doing so, our business will be materially harmed.
- Development of combination therapies may present more or different challenges than development of single agent therapies.
- The use of Oxnimbi or any future product candidates could be associated with side effects, such as insomnia, adverse events ("AEs") or other properties or safety risks that could delay or prevent regulatory approval, limit our market acceptance, if approved, or result in significant negative consequences following marketing approval.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities are lengthy, time consuming and inherently unpredictable and the FDA or comparable foreign authorities may disagree with our regulatory plans, and if we are ultimately unable to obtain regulatory approval for Oxnimbi or any future product candidates, our business will be substantially harmed.
- If our clinical trials fail to demonstrate results satisfactory to the FDA or replicate positive results from earlier preclinical studies or clinical trials conducted by us or by third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize Oxnimbi or any future product candidates.
- The marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approval for the commercialization of Oxnimbi. Furthermore, if there are delays in obtaining regulatory approvals, we may not be able to commercialize our products, may lose competitive lead time and our ability to generate revenues will be materially impaired.
- The commercial success of Oxnimbi will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.
- We currently compete and will in the future continue to compete with other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results.
- Even if we are able to commercialize Oxnimbi, it may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which would harm our business.
- We have engaged in a strategic disposition and our business may suffer if we fail to realize the anticipated benefits from such disposition.
- We have relied on third parties to conduct our clinical trials of Oxnimbi and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of potential future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize Oxnimbi or any future product candidates and our business could be substantially harmed.
- If we are unable to obtain, maintain, enforce or protect intellectual property rights related to Oxnimbi or any future product candidates or technology, we may not be able to compete effectively in our market.

- We in-license key intellectual property necessary for the development of Oxnimbi. If we fail to comply with our obligations in our current and any future intellectual property licenses with third parties, resulting in the termination of such licenses, we could lose rights that are important to our business.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

APNIMED, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
AS OF SEPTEMBER 30, 2026 AND DECEMBER 31, 2025
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 351,826	$ 41,890
Prepaid research and development costs	1,881	1,541
Accounts receivable	588	959
Prepaid expenses and other current assets	6,661	665
Total current assets	360,956	45,055
PROPERTY AND EQUIPMENT, NET	46	66
ASSETS HELD FOR SALE	—	26,893
CONTINGENT ASSET	9,812	—
OPERATING LEASE RIGHT-OF-USE ASSET	652	835
OTHER ASSETS	24	24
TOTAL ASSETS	$ 371,490	$ 72,873
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 4,326	$ 1,788
Accrued expenses and other current liabilities	15,068	11,026
Operating lease liability	273	250
Short-term deferred revenue	17,296	97,812
Total current liabilities	36,963	110,876
LONG TERM LIABILITIES:		
Operating lease liability, net of current	414	623
Convertible notes	—	40,646
Debt	39,059	—
Revenue interest liability	10,297	—
Deposit liability	—	57,120
Deferred revenue	—	15,244
TOTAL LIABILITIES	86,733	224,509
COMMITMENTS AND CONTINGENCIES (NOTE 7)		
Convertible Preferred Stock, $0.00001 par value, no shares and 25,934,116 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 25,934,116 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively. Liquidation preference of $0 and $224,518 as of September 30, 2026 and December 31, 2025, respectively.	—	221,147
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $0.00001 par value, 10,000,000 and no shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares issued or outstanding as of either date.	—	—
Common stock, $0.00001 par value, 500,000,000 shares authorized as of September 30, 2026 and 45,627,228 (42,481,983 Class A, 2,948,668 Class B, and 196,577 Class C) shares authorized as of December 31, 2025; 41,630,779 shares issued and outstanding as of September 30, 2026 and 4,781,256 (1,832,588 Class A, 2,752,091 Class B, and 196,577 Class C) shares issued and outstanding as of December 31, 2025.	1	1
Additional paid-in capital	517,970	24,560
Accumulated deficit	(233,214)	(397,344)
Total stockholders' equity (deficit)	284,757	(372,783)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 371,490	$ 72,873

See notes to unaudited condensed consolidated financial statements.

APNIMED, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2026 AND 2025
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
REVENUE - RELATED PARTY	$ 2,480	$ 8,802	$ 99,374	$ 29,043
OPERATING EXPENSES:				
Research and development	11,812	9,754	29,816	49,179
General and administrative	22,628	6,045	41,808	16,868
Cost of services - related party	245	1,987	3,615	5,028
Total operating expenses	34,685	17,786	75,239	71,075
INCOME (LOSS) FROM OPERATIONS	(32,205)	(8,984)	24,135	(42,032)
OTHER INCOME (EXPENSES):				
Interest income	1,814	263	3,002	1,003
Gain on reversal of deposit liability	—	—	57,120	—
Change in fair value of long-term debt	1,208	—	(451)	—
Change in fair value of revenue interest liability	(260)	—	(720)	—
Change in fair value of convertible notes	—	—	1,315	—
Other expense	(81)	—	(2,819)	—
Total other income	2,681	263	57,447	1,003
NET INCOME (LOSS) FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(29,524)	(8,721)	81,582	(41,029)
Income tax expense	—	—	—	—
NET INCOME (LOSS) FROM CONTINUING OPERATIONS	(29,524)	(8,721)	81,582	(41,029)
Gain on sale of equity method investment	—	—	85,380	—
Loss from discontinued operations	—	(2,189)	(2,832)	(68,001)
NET INCOME (LOSS) FROM DISCONTINUED OPERATIONS	—	(2,189)	82,548	(68,001)
NET INCOME (LOSS)	$ (29,524)	$ (10,910)	$ 164,130	$ (109,030)
Net income (loss) per share - Basic:				
Continuing operations	$ (1.05)	$ (1.83)	$ 6.46	$ (8.62)
Discontinued operations	$ —	$ (0.46)	$ 6.54	$ (14.29)
Basic net income (loss) per share	$ (1.05)	$ (2.29)	$ 13.00	$ (22.91)
Net income (loss) per share - Diluted:				
Continuing operations	$ (1.05)	$ (1.83)	$ 4.75	$ (8.62)
Discontinued operations	$ —	$ (0.46)	$ 4.88	$ (14.29)
Diluted net income (loss) per share	$ (1.05)	$ (2.29)	$ 9.63	$ (22.91)
Weighted average common shares outstanding, basic	28,019,494	4,768,110	12,621,882	4,756,996
Weighted average common shares outstanding, diluted	28,019,494	4,768,110	16,903,129	4,756,996

See notes to unaudited condensed consolidated financial statements.

APNIMED, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (unaudited)

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2026 AND 2025

(in thousands, except share amounts)

	Total Convertible Preferred Stock		Common Stock *See Note 12*		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Outstanding Shares	Amount	Outstanding Shares	Amount			
BALANCE—January 1, 2025	24,224,663	$ 204,890	4,748,644	$ 1	$ 20,537	$ (269,153)	$ (248,615)
Stock based compensation	—	—	—	—	802	—	802
Net loss	—	—	—	—	—	(28,646)	(28,646)
BALANCE—March 31, 2025	24,224,663	$ 204,890	4,748,644	$ 1	$ 21,339	$ (297,799)	$ (276,459)
Stock based compensation	—	—	—	—	866	—	866
Issuance of preferred stock, net of issuance costs of $243	1,709,453	16,257	—	—	—	—	—
Exercise of stock options	—	—	10,191	—	36	—	36
Net loss	—	—	—	—	—	(69,474)	(69,474)
BALANCE—June 30, 2025	25,934,116	$ 221,147	4,758,835	$ 1	$ 22,241	$ (367,273)	$ (345,031)
Stock based compensation	—	—	—	—	1,226	—	1,226
Exercise of stock options	—	—	20,939	—	71	—	71
Net loss	—	—	—	—	—	(10,910)	(10,910)
BALANCE—September 30, 2025	25,934,116	$ 221,147	4,779,774	$ 1	$ 23,538	$ (378,183)	$ (354,644)
BALANCE—January 1, 2026	25,934,116	$ 221,147	4,781,256	$ 1	$ 24,560	$ (397,344)	$ (372,783)
Stock based compensation	—	—	—	—	929	—	929
Issuance of preferred stock, net of issuance costs of $208	2,587,991	24,792	—	—	—	—	—
Exercise of stock options	—	—	14,824	—	16	—	16
Net income	—	—	—	—	—	67,719	67,719
BALANCE—March 31, 2026	28,522,107	$ 245,939	4,796,080	$ 1	$ 25,505	$ (329,625)	$ (304,119)
Stock based compensation	—	—	—	—	1,191	—	1,191
Issuance of warrants, net of issuance costs of $48	—	—	—	—	767	—	767
Exercise of stock options	—	—	5,743	—	45	—	45
Net income	—	—	—	—	—	125,935	125,935
BALANCE—June 30, 2026	28,522,107	$ 245,939	4,801,823	$ 1	$ 27,508	$ (203,690)	$ (176,181)
Issuance of common stock upon initial public offering, net of underwriter discounts, commissions, and issuance costs of $21,899	—	—	13,800,000	—	198,901	—	198,901
Conversion of convertible preferred stock to common stock upon initial public offering	(28,522,107)	$ (245,939)	21,143,116	—	245,939	—	245,939
Conversion of convertible notes upon initial public offering	—	—	2,646,838	—	39,331	—	39,331
Conversion of Class B and Class C common stock upon initial public offering	—	—	(762,851)	—	—	—	—
Stock based compensation	—	—	—	—	6,273	—	6,273
Exercise of stock options	—	—	1,853	—	18	—	18
Net loss	—	—	—	—	—	(29,524)	(29,524)
BALANCE—September 30, 2026	—	$ —	41,630,779	$ 1	$ 517,970	$ (233,214)	$ 284,757

See notes to unaudited condensed consolidated financial statements.

APNIMED, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2026 AND 2025
(in thousands)

	Nine Months Ended September 30, 2026	2025
OPERATING ACTIVITIES:		
Net income (loss)	$ 164,130	$ (109,030)
Stock-based compensation	8,393	2,894
Non-cash lease expense	183	170
Depreciation	20	21
Change in fair value of convertible notes	(1,315)	—
Change in fair value of long-term debt	451	—
Change in fair value of revenue interest liability	720	—
Change in fair value of contingent asset	(35)	—
Debt issuance costs expensed upon issuance of long-term debt recorded using the fair value option	2,845	—
Loss from discontinued operations	2,832	68,001
Gain on sale of equity method investment, discontinued operations	(85,380)	—
Adjustments to reconcile net loss to net cash used in operating activities:		
Prepaid research and development costs	(340)	1,424
Accounts receivable	371	(40)
Prepaid expenses and other current assets	(5,496)	(141)
Accounts payable	2,538	(1,007)
Accrued expenses and other current liabilities	4,042	(6,209)
Deferred revenue	(95,760)	(11,780)
Deposit liability	(57,120)	(7,235)
Operating lease liability	(186)	(165)
Net cash used in operating activities	(59,107)	(63,097)
INVESTING ACTIVITIES:		
Transfer fees related to sale of equity method investment	(336)	—
Proceeds from sale of equity method investment	100,000	—
Net cash provided by investing activities	99,664	—
FINANCING ACTIVITIES:		
Proceeds from issuance of convertible preferred stock	25,000	16,500
Issuance costs of convertible preferred stock	(208)	(243)
Proceeds from initial public offering, net of underwriter discounts and commissions paid	205,344	—
Issuance costs paid for initial public offering	(6,443)	—
Proceeds from issuance of Credit Agreement	48,185	—
Issuance costs of Credit Agreement	(2,845)	—
Proceeds from issuance of warrants	815	—
Issuance costs of warrants	(48)	—
Proceeds from the issuance of long-term convertible notes	—	35,000
Proceeds from exercise of stock options	79	107
Net cash provided by financing activities	269,879	51,364
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	310,436	(11,733)
CASH AND CASH EQUIVALENTS —Beginning of period	41,890	68,350
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—End of period	$ 352,326	$ 56,617
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Conversion of convertible preferred stock to common stock	245,939	—
Conversion of convertible notes to common stock upon initial public offering	39,331	—
Equity method investment obtained in exchange for revenue arrangement (see Note 4)	—	62,200

See notes to unaudited condensed consolidated financial statements.

1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY

Business—Apnimed, Inc., together with its former subsidiary CirqO2, LLC (the "Company" or "Apnimed"), is based in Cambridge, Massachusetts. Apnimed is a late-stage clinical pharmaceutical company dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases. The Company's lead product candidate, AD109 with a proposed proprietary name Oxnimbi™ (aroxybutynin and atomoxetine) tablets, for oral use, ("Oxnimbi"), is an investigational, fixed-dose oral combination of a novel anti-muscarinic and selective norepinephrine reuptake inhibitor for the treatment of obstructive sleep apnea ("OSA") in adults.

Reverse Stock Split—On July 24, 2026, the Company effected a 1-for-1.349 reverse stock split of its issued and outstanding Class A common stock, which also resulted in a proportional adjustment to the conversion ratio for its Class B common stock, Class C common stock and each series of its convertible preferred stock, and to the exercise prices and shares of outstanding stock options and Warrants (as defined in Note 16). Accordingly, all shares of Class A common stock, stock options, Warrants, the as-converted preferred stock, Class B common stock and Class C common stock, and per share information presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split. The per share par value and authorized number of shares of the Company's common stock and preferred stock were not adjusted as a result of the reverse stock split.

Initial Public Offering—In August 2026, the Company completed its initial public offering ("IPO"), in which the Company sold an aggregate of 13,800,000 shares of its common stock, including 1,800,000 shares issued pursuant to the full exercise of the underwriters' overallotment option, at a public offering price of $16.00 per share, resulting in aggregate net proceeds of approximately $198.9 million, after deducting underwriting discounts and commissions and other offering expenses.

In connection with the closing of the IPO, the Company's outstanding convertible preferred stock, Class B common stock, Class C common stock, and Convertible Notes (as defined in Note 3) automatically converted into 25,975,771 shares of Class A common stock. Following the closing of the IPO, all shares of Class A common stock were reclassified and renamed into shares of common stock. No shares of convertible preferred stock, Class B common stock, Class C common stock or Convertible Notes were outstanding after the closing of the IPO. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.00001 per share and 10,000,000 shares of preferred stock, par value $0.00001 per share.

Liquidity—Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital and has financed operations primarily through private equity and debt financings, the Right of First Negotiation Agreement (the "ROFN Agreement", see Note 8) entered into with Shionogi & Co., Ltd. ("Shionogi") during the year ended December 31, 2023 and its IPO.

Apnimed is subject to risks and uncertainties common to early-stage companies in the pharmaceutical industry, including, but not limited to, development by competitors of new therapies, dependence on key personnel, protection of proprietary technology, compliance with government regulations and ability to secure additional capital to fund operations. Oxnimbi may, and any future product candidates will, require significant additional research and development efforts, prior to, and potentially after regulatory approval, if approved. There are also significant efforts associated with preparing for and commercializing any approved product. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company believes its research and development efforts are successful and that it is prepared to commercialize a product candidate, it is uncertain when, if ever, the Company will obtain necessary regulatory approvals and realize significant revenue from product sales.

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within the 12 months after the date that these condensed consolidated financial statements are issued. The Company believes that its existing cash and cash equivalents of $351.8 million as of September 30, 2026, will be sufficient to allow the Company to fund operations at least 12 months from the date that the condensed consolidated financial statements are issued.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are disclosed in Note 2, "Summary of Significant Accounting Policies," in the audited consolidated financial statements for the years ended December 31, 2025 and 2024 and notes thereto, included in the Company's final prospectus for its IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended

(the “Securities Act”) on July 31, 2026 (the “IPO Prospectus”). Since the date of those financial statements, there have been no changes to the Company’s significant accounting policies.

Basis of Presentation—The condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Unaudited Interim Financial Information—The accompanying condensed consolidated balance sheet as of September 30, 2026, and the condensed consolidated statements of operations, and the condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2026 and 2025 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 are unaudited. The condensed consolidated interim financial statements have been prepared in accordance with U.S. GAAP for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's condensed consolidated financial statements as of September 30, 2026, have been included. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026, or for any other subsequent period.

Principles of Consolidation—These unaudited condensed consolidated financial statements include the accounts of CirqO2, LLC. All intercompany amounts have been eliminated in consolidation, and CirqO2 LLC was dissolved in June 2026.

Use of Estimates—The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in developing the estimates including business trends, historical experience and various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources and adjusts those estimates and assumptions when facts and circumstances dictate.

Cash, Cash Equivalents and Restricted Cash—The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

The Company’s cash equivalents, which are funds held in money market accounts, are measured at fair value on a recurring basis. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet which, in aggregate, represents the amount reported in the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025 (in thousands):

	September 30,	
	2026	2025
End of period:		
Cash and cash equivalents	$ 351,826	$ 56,617
Restricted cash included in prepaid expenses and other current assets	500	—
Total cash, cash equivalents and restricted cash	$ 352,326	$ 56,617

Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. The Company regularly invests excess cash with major financial institutions in money market funds and U.S. government securities, all of which can be readily purchased and sold using established markets. As of September 30, 2026 and December 31, 2025, the Company’s cash and cash equivalents were held with two financial institutions. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated, as many of these securities are either government backed or have a high credit rating.

The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection. As of September 30, 2026 and December 31, 2025, all of the Company’s accounts receivable were related to Shionogi-Apnimed Sleep Science, LLC ("SASS"), as discussed in Note 4.

Fair Value of Financial Instruments—Fair value is defined as the price the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair

value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

The Company monitors the availability of inputs that are significant to the measurement of fair value to assess the appropriate categorization of financial instruments within the fair value hierarchy. Changes in economic conditions or model-based valuation techniques may require the transfer of financial instruments from one fair value level to another. In such instances, the Company's policy is to recognize significant transfers between levels at the end of the reporting period. The significance of transfers between levels is evaluated based upon the nature of the financial instrument and size of the transfer relative to total net assets available for benefits.

Deferred Transaction Costs—The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process debt and equity financings as deferred transaction costs until such financings are consummated. After consummation of a debt financing, these costs are presented as a direct deduction from the carrying amount of the related debt liability in the unaudited condensed consolidated balance sheet and are amortized into interest expense over the contractual term of the underlying debt using the effective interest method. After consummation of an equity financing, these costs are recorded to additional paid-in capital as a reduction of the proceeds from the transaction. Should the in-process equity financing be abandoned, the deferred transaction costs would be expensed immediately. There were no deferred transaction costs as of September 30, 2026 and the amounts as of December 31, 2025 were not considered material.

Property and Equipment, Net—Property and equipment, consisting of computers and software, furniture and fixtures, office equipment, and leasehold improvements are stated at cost, less accumulated depreciation. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Such costs are periodically reviewed for recoverability when impairment indicators are present.

Details of property and equipment are presented as follows (in thousands):

	September 30, 2026	December 31, 2025
Computers and software	$ 23	$ 23
Leasehold improvements	94	94
Total	117	117
Accumulated depreciation	(71)	(51)
Property and equipment, net	$ 46	$ 66

Equity Method Investment—The Company utilizes the equity method of accounting to account for an investment in an entity that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. On assessing whether the Company exercises significant influence, the Company considers the nature and magnitude of the investment, the voting and protective rights the Company holds, any participation in the governance of the other entity and other relevant factors.

Under the equity method of accounting, the Company's investments are initially recorded at fair value on the unaudited condensed consolidated balance sheet. Upon initial investment, the Company evaluates whether there are basis differences between the carrying value and fair value of the Company's proportionate share of the investee's underlying assets. To the extent there are basis differences identified, the Company typically amortizes basis differences identified for identifiable assets on a straight-line basis over the underlying assets' estimated useful lives when calculating the attributable earnings or losses, excluding the basis differences attributable to in-process research and development that has no alternative future use. The Company subsequently records in the unaudited condensed consolidated statements of operations its share of income or loss of the other entity within other income and expense, which results in an increase or decrease to the carrying value of the investment. If the share of losses exceeds the carrying value of the Company's investment, the Company will suspend recognizing additional losses and will continue to do so unless it commits to providing additional funding; however, if there are intra-entity profits, this could cause the investment balance to go negative.

The Company evaluates its equity method investments for impairment whenever events or changes in circumstance indicate that a decline in value has occurred that is other than temporary. Evidence considered in this evaluation includes, but would not necessarily be limited to, the financial condition and near-term prospects of the investee, recent operating trends and forecasted performance of the investee, and the Company's strategic plans for holding the investment in relation to the period of time expected for an anticipated recovery of its carrying value. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period, and the investment is written down to fair value.

The Company accounts for its investment in SASS under the equity method of accounting, and no impairment charges were recognized during the nine months ended September 30, 2026 and 2025. Refer to Notes 4 and 15 for further discussion.

Fair Value Option—The Company accounted for certain freestanding instruments identified in the Credit Agreement that were debt host financial instruments under the fair value election of Accounting Standards Codification ("ASC") 825, *Financial Instruments*. See Note 16 for more information. These instruments were recorded at their estimated fair values on the issuance date and will be remeasured to their estimated fair value at each subsequent reporting period date. The Tranche A Term Loan and Tranche B Term Loan (each as defined in Note 16) includes embedded features that are not separately accounted for as a result of the Company's fair value option election.

Changes in the estimated fair value are recorded in other expense, net, on the condensed consolidated statement of operations, except changes in estimated fair value caused by changes in the instrument-specific credit risk which are recorded in other comprehensive (loss) income. As a result of electing the fair value option, related direct costs and fees are expensed as incurred.

Common Stock Warrants—The Company determines the accounting classification of warrants it issues, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("ASC 480-10") and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ("ASC 815-40"). Under ASC 480-10, warrants are considered liability classified if the shares underlying the warrants are mandatorily redeemable, obligate the Company to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing a variable number of shares.

If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, and in order to conclude equity classification, the Company also assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable U.S. GAAP. After all relevant assessments, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance, with all changes in fair value after the issuance date recorded in the condensed consolidated statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date.

Revenue Recognition—The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

From time to time, the Company enters into license and research and development agreements that are within the scope of ASC 606, under which the Company licenses, may license, or grants an option to license rights to certain of the Company's product candidates or performs research and development services (see Note 4). The terms of these agreements typically include payment of one or more of the following: non-refundable, up-front fees; developmental, clinical, regulatory, and commercial sales milestone payments; royalties on net sales of licensed products and research and development funding payments.

In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized, for agreements within the scope of ASC 606, the Company performs the following five steps: (i) identification of the contract with the customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the separate performance obligations in the contract; and (v) recognize revenue associated with performance obligations as they are satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's agreements typically consist of a license, or option to license, rights to the Company's intellectual property or research and development services. Performance obligations are promises in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available, and whether the goods or services are integral or dependent on other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each agreement that includes variable consideration, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments that are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and clinical milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration and other research and development revenue in the period of adjustment.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration or strategic alliance agreements.

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

Changes in scope of the promised goods or services, or changes in consideration which the Company expects to receive related to existing contracts are recorded as contract modifications. Contract modifications are recorded as a separate contract if the scope of the contract increases because of the addition of promised goods or services that are distinct, and the price of the contract increases by an amount of consideration that reflects the Company's standalone selling price of the additional promised goods or services. Contract modifications which result in remaining goods or services distinct from those already provided are treated as a termination of the existing contract and a creation of a new contract whereby the remaining transaction price from the existing contract is allocated to the remaining goods and services. Contract modifications which result in goods or services which are not distinct from those already provided are treated as an update to the transaction price and measure of progress for the single performance obligation as a cumulative catch-up to revenue.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these

arrangements. Deferred revenue that is anticipated to be recognized within the next 12 months is recorded as the current portion of deferred revenue and the remaining portion is included in long-term liabilities as deferred revenue on the unaudited condensed consolidated balance sheets. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Income Taxes—Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax assets will not be realized.

The Company has evaluated significant tax positions against the criteria established by professional standards and concluded there are no such tax positions requiring accounting recognition in the unaudited condensed consolidated financial statements. The Company further maintains a full valuation allowance against all deferred tax assets. If the Company were to incur interest and penalties on uncertain tax positions, it would classify them as income tax expense. The tax returns are subject to examination by taxing authorities generally for three years from the filing date.

For the nine months ended September 30, 2026, the Company recognized net income of $164.1 million compared to net loss of $109.0 million for the nine months ended September 30, 2025. The primary reconciling item between the federal statutory rate of 21.0% for the nine months ended September 30, 2026, and the Company's overall effective tax rate of 0.0% was the effect of deferred revenue and the valuation allowance recorded against its net deferred tax assets.

Discontinued Operations and Held for Sale—The Company classified long-lived assets, components or other disposal groups as held for sale in accordance with ASC 360, *Property, Plant, and Equipment*. A component is classified as held for sale when management having the authority to approve the action commits to a plan to sell the component, the component is available in its present condition, and the sale is probable to occur during the next 12 months at a price that is reasonable in relation to its current fair value. Assets or disposal groups classified as held for sale are reported at the lower of their carrying amount or estimated fair value less costs to sell. When the carrying amount of the disposal group exceeds its estimated fair value less costs to sell, a loss is recognized and updated each reporting period.

The results of operations of a component classified as held for sale are reported as discontinued operations in accordance with ASC 205-20, *Presentation of Financial Statements - Discontinued Operations*, if the disposal represents a strategic shift that will have a major effect on the Company's operations and financial results. When a component is identified for discontinued operations reporting: (i) results for prior periods are retrospectively reclassified to discontinued operations; (ii) results of operations are reported in a single line separately from the gain on disposal of the Company's equity method investment, net of tax, in the unaudited condensed consolidated statements of operations; and (iii) assets and liabilities are reported as held for sale in the unaudited condensed consolidated balance sheets in the period in which the business is classified as held for sale.

Net Income (Loss) per Share—Basic net income (loss) per share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive.

Basic and diluted income (loss) per share are presented separately from income (loss) from continuing operations and discontinued operations, when applicable, in accordance with ASC 260, *Earnings per share*. The calculation of income (loss) per share attributable to discontinued operations reflects the income or loss from discontinued operations, net of applicable taxes, attributable to common stockholders for the applicable reporting period.

Prior to the completion of the Company's IPO in August 2026, the Company had Class A, Class B and Class C common stock outstanding. During this period, the Company used the two-class method to compute net loss per share relating to the Company's multiple classes of common stock. The two-class method requires losses for the period to be allocated between classes of common stock based upon their respective rights to participate in undistributed losses of the Company.

Under the two-class method, basic net loss per share was computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period.

In connection with the closing of the IPO, all outstanding shares of convertible preferred stock, Class B and Class C common stock and Convertible Notes automatically converted into Class A common stock. Following the closing of the IPO, all shares of Class A common stock were reclassified and renamed into shares of common stock. For periods subsequent to the IPO, basic net income (loss) per share is calculated based on the weighted average number of common shares outstanding during the period.

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for the three months ended September 30, 2026 and 2025, as well as the nine months ended September 30, 2025.

Diluted weighted average shares outstanding are calculated using the treasury stock method for stock options and other potentially dilutive securities, and the if-converted method for convertible instruments such as convertible notes and convertible preferred stock.

The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2026 are as follows:

	Three months ended September 30, 2026	Nine months ended September 30, 2026
(in thousands, except share and per share information)		
Numerator:		
Net (loss) income from continuing operations, basic	$ (29,524)	$ 81,582
Less: change in fair value of convertible notes	—	(1,315)
Net (loss) income from continuing operations, diluted	$ (29,524)	$ 80,267
Net income from discontinued operations, basic and diluted	$ —	$ 82,548
Denominator:		
Weighted average common stock outstanding, basic	28,019,494	12,621,882
Options to purchase common stock	—	4,153,173
Dilutive effect of stock options exercised/canceled during the period	—	127,957
Warrants (defined in Note 16)	—	117
Weighted average common stock outstanding, diluted	28,019,494	16,903,129
Net income (loss) per share - Basic:		
Continuing operations	$ (1.05)	$ 6.46
Discontinued operations	$ —	$ 6.54
Basic net income (loss) per share	$ (1.05)	$ 13.00
Net income (loss) per share - Diluted:		
Continuing operations	$ (1.05)	$ 4.75
Discontinued operations	$ —	$ 4.88
Diluted net income (loss) per share	$ (1.05)	$ 9.63

The components of basic and diluted net loss per share for the three and nine months ended September 30, 2025 are as follows:

	Three months ended September 30, 2025	Nine months ended September 30, 2025
(in thousands, except share and per share information)		
Numerator:		
Net loss from continuing operations, basic and diluted	$ (8,721)	$ (41,029)
Net loss from discontinued operations, basic and diluted	$ (2,189)	$ (68,001)
Denominator:		
Weighted average common stock outstanding, basic and diluted [1]	4,768,110	4,756,996
Net loss per share of common stock, basic and diluted		
Continuing operations	$ (1.83)	$ (8.62)
Discontinued operations	$ (0.46)	$ (14.29)

(1) Prior to the completion of the Company's IPO in August 2026, the Company had Class A, Class B and Class C common stock outstanding.

The Company's potentially dilutive securities, which include certain outstanding stock options and convertible preferred stock and warrants, have been excluded from the computation of diluted net income (loss) per share when they are anti-dilutive. The following table sets forth the outstanding potentially dilutive securities which have been excluded from the computation of diluted weighted average shares outstanding:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Convertible preferred stock	—	25,934,116	—	25,934,116
Options to purchase common stock	10,914,655	6,783,196	6,761,479	6,783,196
Warrants (defined in Note 16)	100,163	—	—	—
	11,014,818	32,717,312	6,761,479	32,717,312

Recently Issued Accounting Pronouncements Not Yet Adopted—In December 2025, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2025-12, *Codification Improvements.* ("ASU 2025-12"). The guidance clarifies, corrects errors in or makes other improvements to a variety of topics in the Accounting Standards Codification that are intended to make it easier to understand and apply. The amendments apply to all reporting entities in the scope of the affected accounting guidance. ASU 2025-12 is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. It can be adopted using either a prospective or retrospective method, and early adoption is permitted. The Company is currently evaluating the effect of adopting ASU 2025-12 on its disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* ("ASU 2025-11"). The amendments clarify the scope of interim reporting guidance in U.S. GAAP, consolidate interim disclosure requirements from other codification topics, and introduce a disclosure principle requiring entities to describe events occurring after the end of the most recent annual period that have a material effect on the entity. The ASU is effective for annual periods beginning after December 15, 2027 and for interim periods within fiscal years beginning after December 15, 2028. Early adoption is permitted. The Company is currently evaluating the effect of this update; however, because the amendments primarily clarify existing interim reporting requirements and do not significantly expand disclosure obligations, the Company does not expect the ASU to have a material impact on its condensed consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40) - Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The ASU requires, among other items, additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the unaudited condensed consolidated statements of operations. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating the effect of adopting the ASU on its disclosures.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, to incorporate several SEC disclosure requirements into a variety of topics in the FASB codification. These amendments align the requirements in the ASC with the removal of certain disclosure requirements set out in Regulation S-X and Regulation S-K, announced by the SEC. The effective date for each amended topic in the ASC is either the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, or on June 30, 2027, if the SEC has not removed the requirements by that date. Early adoption is prohibited. The Company does not expect that the application of this standard will have a material impact on its condensed consolidated financial statements or disclosures.

3. FAIR VALUE MEASUREMENT

The following table sets forth the recurring fair value of the Company's financial assets, allocated into the Level 1, Level 2 and Level 3 hierarchy that were measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds [(1)]	$ 36,806	$ —	$ —	$ 36,806
Contingent asset	—	—	9,812	9,812
Total financial assets	$ 36,806	$ —	$ 9,812	$ 46,618
Liabilities:				
Long-term debt	$ —	$ —	$ 39,059	$ 39,059
Revenue interest liability	—	—	10,297	10,297
Total financial liabilities	$ —	$ —	$ 49,356	$ 49,356

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds [(1)]	$ 37,492	$ —	$ —	$ 37,492
Total financial assets	$ 37,492	$ —	$ —	$ 37,492
Liabilities:				
Convertible notes	$ —	$ —	$ 40,646	$ 40,646
Total financial liabilities	$ —	$ —	$ 40,646	$ 40,646

(1) Included in cash and cash equivalents in the accompanying unaudited condensed consolidated balance sheets.

There were no net unrealized gains or losses on investments as of September 30, 2026 or December 31, 2025. The carrying value of accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

In September 2025, the Company issued convertible notes (the "Convertible Notes") with a principal amount of $35.0 million (see Note 9). The Company concluded that the Convertible Notes and its related features are within the scope of ASC 825, as a combined financial instrument, and elected the fair value option, where changes in fair value of the Convertible Notes are measured through the consolidated statement of operations until settlement. The Convertible Notes were recorded at their estimated fair value of $35.0 million in the unaudited condensed consolidated balance sheet at inception. The Convertible Notes liability represents a Level 3 measurement within the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include the underlying fair value of the equity instrument into which the Convertible Notes are convertible. The fair value of the Convertible Notes is based on significant inputs not observable in the market, namely potential financing scenarios, the likelihood of such scenarios, the expected time for each scenario to occur, and the required market rates of return utilized in modeling these scenarios.

In August 2026, the Company completed its IPO, which resulted in the conversion of all outstanding Convertible Notes, including accrued interest, into 2,646,838 shares of common stock. The carrying value of the Convertible Notes immediately prior to conversion was approximately $39.3 million. The Company assessed the fair value of the Convertible Notes immediately prior to conversion and concluded that there was no material change in fair value from June 30, 2026 through the conversion date.

During the three months ended September 30, 2026, the Company did not recognize a gain or loss related to changes in the estimated fair value of the Convertible Notes. During the nine months ended September 30, 2026, the Company recorded a gain of $1.3 million related to the change in estimated fair value of the Convertible Notes. There was no change in fair value attributable to the instrument-specific credit risk.

On April 2, 2026, the Company entered into the Credit Agreement whereby the Lenders advanced $50.0 million related to the Tranche A Term Loan to the Company, net of a $1.0 million discount. In connection with the Credit Agreement, the Company issued warrants to purchase an aggregate of 100,163 shares of the Company's Class A common stock and is also obligated to remit to the Lenders certain revenue interest payments on net sales of Oxnimbi (the "Revenue Interest"). See Note 16 for defined terms and additional information. The total proceeds received of $49.0 million were allocated between the warrants issued, the Tranche A Term Loan and the Revenue Interest based on the fair value at issuance date. The Tranche A Term Loan, recorded as long-term debt on the unaudited condensed consolidated balance sheet, and Revenue Interest were recorded at their estimated fair values of $38.6 million and $9.6 million, respectively, in the unaudited condensed consolidated balance sheet at April 2, 2026, the issuance date. The fair values were determined using a Monte Carlo simulation model incorporating Level 3 unobservable inputs, including the probability of FDA approval of Oxnimbi, estimated future net revenues, and various settlement scenarios, the likelihood of such scenarios, the expected time for each scenario to occur, and the required market rates of return utilized in modeling these scenarios. Significant

increases or (decreases) in these inputs would generally result in higher (lower) fair value measurement. These inputs are not evaluated in isolation, as changes in one unobservable input may be accompanied by directionally similar or opposite changes in another.

The Tranche A Term Loan and Revenue Interest were recorded at their estimated fair value of $39.1 million and $10.3 million, respectively, within the unaudited condensed consolidated balance sheet as of September 30, 2026. The Company recorded a loss of $0.5 million and $0.7 million related to the change in estimated fair value of the Tranche A Term Loan and the Revenue Interest liability, respectively, during the nine months ended September 30, 2026, and a gain of $1.2 million and loss of $0.3 million related to the estimated fair value of the Tranche A Term Loan and Revenue Interest liability, respectively, during the three months ended September 30, 2026. There was no change in fair value attributable to the instrument-specific credit risk for the three and nine months ended September 30, 2026.

On March 23, 2026, the Company entered into a definitive agreement, and in April 2026, the Company completed the SASS Disposition pursuant to the MIPA, as discussed further in Note 4. Upon completion of the SASS Disposition, the Company initially recognized and measured the fair value of the contingent asset representing the potential receipt of an additional $50.0 million milestone payment that the Company is eligible to receive, subject to the earlier achievement of a specified clinical development milestone or a probability-weighted discounted cash flow model incorporating Level 3 unobservable inputs, including estimated probability and timing of achieving the milestone and discounted present value at a rate reflecting both the time value of money and the counterparty's credit risk. A significant increase (decrease) in the estimated probability of achieving the Milestone would result in a significantly higher (lower) fair value measurement, as fair value scales approximately linearly with the assumed probability of success. A significant increase (decrease) in the estimated time to payment, the risk-free rate, or the counterparty credit spread would result in a lower (higher) fair value measurement, as each lengthens (shortens) the effective discounting period or increases (decreases) the discount rate applied. Because the probability of achievement is derived from industry-wide historical clinical development success rates rather than an asset-specific estimate, actual outcomes for this particular Milestone could differ materially from the probability applied.

The following tables present additional information about level 3 contingent asset, long-term debt, Revenue Interest, and Convertible Notes measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements - Level 3				
	Assets	Liabilities			
	Contingent asset	Long-term debt	Revenue interest	Convertible notes	Total
Balance as of January 1, 2026	$ —	$ —	$ —	$ 40,646	$ 40,646
Issuance of contingent asset, long-term debt, and revenue interest	9,777	38,608	9,577	—	57,962
Changes in fair value	35	451	720	(1,315)	(109)
Conversion of convertible notes	—	—	—	(39,331)	(39,331)
Balance as of September 30, 2026	$ 9,812	$ 39,059	$ 10,297	$ —	$ 59,168

	Fair Value Measurements - Level 3				
	Assets	Liabilities			
	Contingent asset	Long-term debt	Revenue interest	Convertible notes	Total
Balance as of January 1, 2025	$ —	$ —	$ —	$ —	$ —
Issuance of convertible notes	—	—	—	35,000	35,000
Changes in fair value	—	—	—	5,646	5,646
Balance as of December 31, 2025	$ —	$ —	$ —	$ 40,646	$ 40,646

4. EQUITY-METHOD INVESTMENT

On October 31, 2023 (the “Closing Date”), the Company and Shionogi created a joint venture, SASS, for the purpose of conducting research and development activities to treat, prevent, and mitigate OSA and other sleep breathing diseases. In April 2026, the Company completed the disposition of the Company's interest in SASS (the "SASS Disposition") to Shionogi pursuant to a Membership Interest and Asset Purchase Agreement (the “MIPA”), as described more fully below in this Note 4.

In the formation of the joint venture, the Company contributed an exclusive license to SASS for intellectual property and know-how related to certain of the Company's sleep and breathing disease programs, and executed a Master Services Agreement (as amended on January 1, 2025, the "MSA"). Under the MSA, SASS contracted with the Company for various services including research and development services. In exchange for the contributed intellectual property, the Company received 50% ownership in SASS. Shionogi contributed $75.0 million in cash and an exclusive license for certain intellectual property related to certain of its sleep programs, and executed a Master Services Agreement with SASS (the "Shionogi MSA"). In exchange, Shionogi received 50% ownership in SASS.

The initial term of SASS was five years ("Initial Term"), extendable for additional periods with the agreement of both the Company and Shionogi or in order to continue commercialization or monetization activities commenced prior to expiration of the term of the joint venture. The Company and Shionogi were each entitled to designate three individuals to the SASS board of managers. Membership interests generally could not be transferred prior to the expiration of the Initial Term, subject to limited exceptions.

The Company had significant influence over, but did not control, SASS through its noncontrolling representation on SASS's board of managers and the Company's equity interest in SASS. The Company was not the primary beneficiary as it did not have the power to solely direct the activities of SASS that most significantly impacted SASS's economic performance. Accordingly, the Company did not consolidate the financial statements of SASS and accounted for its investment using the equity method of accounting.

The Company recorded its equity method investment in SASS at fair value as of the Closing Date. The initial fair value of the Company's investment was $75.0 million, which represented the fair value of the equity received. The Company recorded the initial investment of $75.0 million on its consolidated balance sheet and recognized deferred revenue (refer to Note 10).

In April 2025, the Company entered into an asset purchase and license agreement (the "Desitin APA") with Desitin Arzneimittel GmbH ("Desitin") and Cereus Pharma AB ("Cereus"), pursuant to which Apnimed (i) purchased certain patents and know-how related to sulthiame (the "Purchased Sulthiame IP") and (ii) obtained a perpetual, irrevocable, exclusive and fully paid-up license to know-how controlled by Desitin concerning the manufacturing of products using sulthiame in the field of diagnosis, prevention, treatment, mitigation or control of sleep apnea and all other sleep diseases, disorders and conditions in humans including obesity hypoventilation syndrome (the "Licensed Sulthiame IP") in exchange for an upfront cash consideration of $50.0 million, (collectively the "Desitin IP"). In addition to the upfront $50.0 million, upon achievement of certain development and regulatory milestones, the Company was previously required to pay the Milestone Payments (as defined below in Note 7) and the Company was also previously required to make the Earnout Payment (as defined below in Note 7) under certain circumstances. However, in connection with the SASS Disposition, the Desitin APA was novated to Shionogi such that the Company was released as a party to the Desitin APA with respect to obligations accruing on or after the closing of the SASS Disposition, with Shionogi agreeing to be solely liable for such obligations other than confidentiality obligations and certain other limitations on activities.

In July 2024, Shionogi exercised its right of first negotiation with respect to certain intellectual property covered under the ROFN Agreement (Note 8), referred to herein as "Optioned Selective NRI/CAI IP". Negotiations ensued pursuant to the exercise of such right of first negotiation with respect to the Optioned Selective NRI/CAI IP and in April 2025, the Company and Shionogi entered into a joint ownership agreement (the "Joint Ownership Agreement") and a SASS CAI and Selective NRI/CAI Contribution Agreement with SASS (the "Contribution Agreement").

Pursuant to the Joint Ownership Agreement in April 2025, Apnimed granted to Shionogi (i) a 50% joint ownership interest in the Purchased Sulthiame IP, (ii) a co-exclusive license under the Licensed Sulthiame IP and (iii) a co-exclusive license under certain intellectual property in respect of the compound atomoxetine ("Atomoxetine Licensed IP", and together with the intellectual property described in subsections (i) and (ii), the "Joint Ownership IP"). In addition to rights in the Joint Ownership IP, Shionogi was granted an exclusive right, exercisable at any time during the term of the Contribution Agreement to negotiate for additional rights over the Joint Ownership IP controlled by SASS to develop, manufacture or commercialize a product in Japan, South Korea, and Taiwan and the People's Republic of China (the "Shionogi Option"). Shionogi paid Apnimed $55.0 million upon execution of the Joint Ownership Agreement.

Pursuant to the Contribution Agreement, the Company and Shionogi contributed the Joint Ownership IP to SASS which also resulted in the Milestone Payments and Earnout Payment due pursuant to the Desitin APA being assigned to SASS as discussed further in Note 7.

The accounting for the Desitin APA, the ROFN Agreement exercise, the Joint Ownership Agreement and the Contribution Agreement, collectively is as follows:

- Upon executing the Joint Ownership Agreement in April 2025, the Company received $55.0 million from Shionogi. The Company allocated $25.0 million to the Desitin IP and allocated the remaining $30.0 million between the Shionogi Option and the fair value of Shionogi's 50% share of the Atomoxetine Licensed IP, representing $7.5 million and $22.5 million, respectively. The Shionogi Option was recorded as a deposit liability (see Note 8) and the fair value of the Atomoxetine Licensed IP was recorded as deferred revenue (see Note 10).

- The Desitin IP was not within the scope of ASC 730, *Research and Development* ("ASC 730") as it was purchased with the intent to be immediately contributed to SASS. As Shionogi purchased 50% of the rights over the Desitin IP, the Company's contribution of the Desitin IP to SASS resulted in an increase to the equity method investment in SASS of $25.0 million.
- Upon the execution of the Contribution Agreement, the Company and Shionogi each contributed such party's share of the Joint Ownership IP into SASS. The Company accounted for the contribution of its share of the Joint Ownership IP to SASS under ASC 606 as described within Note 10. In accordance with ASC 606, the Company reclassified $14.7 million of the initial deposit liability recorded as of December 31, 2024, to deferred revenue using the relative fair value method relating to the Atomoxetine Licensed IP as described in Note 10.
- The Joint Ownership IP contributed to SASS resulted in an increase to the equity method investment of $62.2 million, of which $25.0 million was allocated to the Desitin IP and $37.2 million was allocated to the Atomoxetine Licensed IP. Of the amounts allocated to the Atomoxetine Licensed IP, $14.7 million was reclassified from the initial deposit liability and $22.5 million from the cash received upon execution of the Joint Ownership Agreement.
- SASS accounted for the contribution of the Desitin IP and the Atomoxetine Licensed IP under ASC 730, recording expense equal to the fair value of the contributions as the contributions represented in-process research and development ("IPR&D") with no alternative future use. The Company recorded its 50% share of the losses from the IPR&D as a reduction of its carrying value of the equity method investment in SASS of $62.2 million.

The roll-forward of 2025 and 2026 activity is as follows (in thousands):

Beginning Balance January 1, 2025	$	34,796
Additions:		
Contribution of Desitin IP		25,000
Contribution of Atomoxetine Licensed IP		37,200
Total		62,200
SASS Net loss allocation		
IPR&D write-off		(62,200)
Share of other net loss		(7,903)
Total		(70,103)
Ending Balance December 31, 2025		26,893
SASS Net loss allocation		(2,654)
Ending Balance March 31, 2026	$	24,239
SASS Net loss allocation		(178)
Ending Balance April 6, 2026	$	24,061
MIPA		(24,061)
Ending Balance September 30, 2026	$	-

On March 23, 2026, the Company entered into a definitive agreement, and in April 2026, the Company completed the SASS Disposition pursuant to the MIPA. The Company had recorded its equity method investment in SASS as assets held for sale within its consolidated balance sheets as of December 31, 2025 and March 31, 2026, as discussed in Note 15. As consideration under the MIPA, the Company received a $100 million upfront cash payment and will be eligible to receive (a) a $50 million cash payment upon the earlier achievement of (i) the first subject being enrolled into the second clinical trial of a sulthiame product sponsored by Shionogi, SASS or either of their licensees, sublicensees, or affiliates (each an Earnout Party and collectively, the Earnout Parties) and (ii) U.S. Food and Drug Administration ("FDA") acceptance of a New Drug Application for a sulthiame product submitted by an Earnout Party and (b) tiered earnout payments equal to mid to low single digit percentage of net sales of certain products arising from SASS intellectual property.

The Company accounted for the disposition of its 50% equity ownership in SASS in accordance with ASC 860, *Transfers and Servicing of Financial Assets*, as the Company relinquished all ownership interests and effective control over SASS upon closing, and the consideration received does not convey continuing involvement beyond customary contingent payments. Accordingly, the Company accounted for the transaction as a sale, derecognized its equity method investment, and recognized a gain in earnings based on the difference between the consideration received, which includes the contingent milestone-based payment and the sale-based royalties, and the carrying value of the investment at the time of transfer. Prior to the disposition, the Company had accounted for its investment under the equity method. The Company measured the fair value of the additional $50.0 million milestone payment that the Company is eligible to receive, subject to the earlier achievement of a specified clinical development milestone or a specified regulatory milestone at $9.8 million based on a probability-weighted discounted cash flow model as of the date the transaction closed.

The fair value of the sale-based royalty payments was determined to be de minimis as of the closing date and as of September 30, 2026. For subsequent measurement, the Company elected the fair value option under ASC 825-10 to remeasure the contingent milestone payment and the sale-based royalty payments at fair value each reporting period, with changes in fair value recognized in earnings as they arise. The Company remeasured the milestone payment and sales-based royalty payments to their estimated fair value of $9.8 million and $0, respectively, included in contingent assets within the unaudited condensed consolidated balance sheet as of September 30, 2026. The resulting change in fair value was determined to be de minimis and was recorded as other income in the unaudited condensed statement of operations for the nine months ended September 30, 2026. The corresponding gain on sale of equity method investment of $85.4 million for the nine months ended September 30, 2026 reflects the difference between (i) the $100.0 million upfront cash consideration received and the estimated fair value of $9.8 million attributable to the contingent asset associated with the one-time milestone payment and (ii) the investment's carrying value of $24.1 million at April 6, 2026, the date of disposition, net of direct transaction costs incurred of $0.3 million.

In connection with the SASS Disposition, (i) Shionogi, SASS and the Company released Shionogi and SASS, in each case, from all claims with respect to periods prior to the MIPA, subject to certain exceptions, (ii) the Company was removed as a party to the SASS amended and restated limited liability company agreement for all purposes other than in relation to indemnification obligations to directors and officers and certain tax matters and (iii) the ROFN Agreement was terminated other than confidentiality obligations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Employee compensation costs	$ 6,294	$ 6,074
Professional costs	5,454	2,370
Research and development costs	3,084	2,021
Severance	70	475
Other	166	86
Total accrued expenses and other current liabilities	$ 15,068	$ 11,026

In March 2026 and October 2025, the Company executed separate reduction-in-force plans (“RIFs”) whereby certain positions were terminated. The one-time termination benefits under the RIFs were recorded in accordance with ASC 420, *Exit and Disposal Obligations.*

6. OPERATING LEASE

As of September 30, 2026 and December 31, 2025, the Company was a party to a property lease in Cambridge, Massachusetts. The Company entered into the lease with a related party for office space in June 2023. The term of the lease is 60 months from the commencement date of January 26, 2024, when the new office space was available for use by the Company. The lease expires in January 2029. The lessor is considered a related party as the entity is an affiliate of a stockholder in the Company.

The lease agreement obligates the Company to pay Cambridge city taxes, insurance and certain maintenance costs (hereinafter referred to as non-lease components).

The following table presents the classification of the right-of-use assets and operating lease liabilities (in thousands):

	September 30, 2026	December 31, 2025
Assets		
Operating lease right-of-use assets	$ 652	$ 835
Liabilities		
Operating lease liabilities, current	$ 273	$ 250
Operating lease liabilities, non-current	414	623
Total lease liabilities	$ 687	$ 873

Rent expense and cash paid for leases included in operating cash flows for both the nine months ended September 30, 2026 and 2025 was $0.2 million.

The following represents a summary of the Company's future minimum lease payments under non-cancelable lease agreements, presented in accordance with ASC 842 (in thousands), as of September 30, 2026.

2026 (remaining three months)	$	78
2027		319
2028		328
2029		27
Total future minimum lease payments	$	752
Less: amount representing interest		(65)
Present value of operating lease liabilities	$	687
Less: Operating lease liabilities, current		(273)
Operating lease liabilities, non-current	$	414
Remaining lease term (in years)		2.3
Incremental borrowing rate		8.13%

7. COMMITMENTS AND CONTINGENCIES

BWH License Agreement—The Company signed an Exclusive Patent License Agreement with the Brigham and Women's Hospital, Inc. ("BWH"), now a subsidiary of Mass General Brigham, Inc., on June 19, 2018 (as amended and restated on December 29, 2020 and further amended on July 27, 2023, the "BWH License"). Under the BWH License, the Company is required to make milestone payments up to $8.6 million upon achievement of certain development, regulatory and commercial milestones across three different products including Oxnimbi. Subject to an annual minimum royalty amount that is creditable against royalties earned in the same calendar year for which the minimum royalty is paid, the Company agreed to pay BWH royalties equal to a low single digit percentage of net sales of the products covered by the BWH License and a tiered low double-digit percentage of revenue that the Company receives from sublicensing. If the Company undergoes a change of control, the Company will be required to pay BWH at least $0.3 million and as much as $0.5 million, depending on the patents and patent applications that remain licensed to the Company on the effective date of the change of control.

No fees associated with the agreement with BWH were paid during the nine months ended September 30, 2026 and 2025.

Desitin APA— In April 2025, the Company entered into the Desitin APA with Desitin and Cereus, pursuant to which it purchased the Purchased Sulthiame IP and obtained a perpetual, irrevocable exclusive, and fully paid-up license to the Licensed Sulthiame IP. As consideration under the Desitin APA, the Company paid Desitin an upfront amount of $50.0 million. In addition to the upfront $50.0 million, upon achievement of certain development and regulatory milestones, the Company was previously required to pay Desitin up to $85.0 million in the aggregate (the "Milestone Payments"). The Company was also previously required to make certain earnout payments to Desitin based on set percentages of net sales if product approval is obtained. The earnout payments to Desitin, included (i) a sub-teen double-digit percentage of net sales of a product if its only active pharmaceutical ingredient is sulthiame and is covered by a purchased patent (a "Patented Product"), (ii) a high single-digit percentage of net sales of a product containing as its active ingredients both sulthiame and one or more other active ingredients and is covered by a purchased patent (a "Combination Product") and (iii) a mid-single digit percentage of net sales of a Combination Product indicated for the prevention, treatment or control of obesity hypoventilation syndrome, each subject to reduction in the event of lack of patent protection or generic competition (the "Product Earnout Payments"). During the five-year period following the first commercial launch of any Patented Product or Combination Product (such period, the "Restricted Period"), the Company and its affiliates and licensees were not permitted to market or sell any competing product in countries in which the Company or its affiliates or licensees have effected a commercial launch of such Patented Product or Combination Product. However, the Company and its affiliates, licensees and sublicensees were permitted to market, commercially distribute and sell a competing product in each such country that the selling party determines to be a superior product for commercialization in such country subject to paying Desitin a mid-single digit percentage of net sales of such Competing Product generated during the remainder of the Restricted Period (together with the Product Earnout Payments, the "Earnout Payments"). As discussed in Note 4, the Earnout Payment and the Milestone Payments were assigned to SASS.

Legal Proceedings—The Company is not currently a party to any material legal proceedings that are currently pending or threatened and the Company was not subject to any material legal proceedings during the nine months ended September 30, 2026 and 2025. However, from time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred.

8. DEPOSIT LIABILITY

On November 1, 2023, the Company entered into the ROFN Agreement and a Common Stock Purchase Agreement with Shionogi, receiving total combined consideration of $75.0 million from Shionogi. Pursuant to the ROFN Agreement, the Company granted Shionogi a right of first negotiation with respect to up to three product candidates (each, a "ROFN Program") as well as a right to receive notice of unsolicited offers for such sleep and breathing disease programs during the Initial Term of SASS (see Note 4). In evaluating the nature of the ROFN Agreement under ASC 606, the Company concluded the ROFN Agreement did not represent a contract with a customer as the Company was not legally or contractually obligated to transfer any goods or services at the time the ROFN Agreement was signed. Therefore, the consideration received was recognized as a deposit liability. The deposit liability represents the Company's obligation to transfer either goods or services in the future if and when agreements are executed. The deposit liability is expected to be recognized as revenue in future periods only if an ASC 606 contract is entered into as a result of negotiations under the ROFN Agreement. If the Company does not enter a revenue generating arrangement during the Initial Term for all ROFN Programs, any remaining deposit liability will be recorded as income in the statement of operations.

The total combined transaction price was $75.0 million. Using the relative fair value method, the Company allocated $64.4 million to the ROFN Agreement representing the nonrefundable negotiation rights received, the full amount of which was recorded as a deposit liability at December 31, 2023, with the remainder allocated to common stock. Refer to Note 12 for details of common stock issued.

In July 2024, Shionogi exercised its right to negotiate with respect to the Optioned Selective NRI/CAI IP under the ROFN Agreement. Negotiations ensued and in April 2025, the Company and Shionogi entered into the Joint Ownership Agreement and the Contribution Agreement (see Note 4). The Company accounted for contribution of the Joint Ownership IP to SASS under ASC 606. In accordance with ASC 606, the Company reclassified $14.7 million of the initial deposit liability recorded as of December 31, 2024 to deferred revenue using the relative fair value method relating to the Atomoxetine Licensed IP which was contributed to SASS pursuant to the Contribution Agreement. To determine the relative fair value, the Company utilized a cost incurred methodology. Pursuant to the Joint Ownership Agreement, Shionogi was granted the Shionogi Option. Of the $55.0 million received from Shionogi in connection with the Joint Ownership Agreement, the Company allocated $7.5 million to the Shionogi Option under the relative fair value method, as an additional deposit liability within the consolidated balance sheet as of December 31, 2025. See Note 4 for discussion of the accounting for the remaining amount received from Shionogi in connection with the Joint Ownership Agreement.

In April 2026, the Company terminated the ROFN Agreement. The termination of the ROFN Agreement was made without entering into a customer contract in accordance with ASC 606. As no revenue generating arrangement was made related to the remaining rights under the ROFN Agreement prior to its termination, and the Company does not have any future negotiation obligation, the deposit liability of $57.1 million was derecognized and recorded as a gain on reversal of deposit liability.

9. CONVERTIBLE NOTES

In September 2025, the Company issued Convertible Notes to various investors in the principal amount of $35.0 million. The Convertible Notes bore an interest rate of 8% per annum through March 31, 2026. The Convertible Notes were not converted prior to March 31, 2026 and bore an interest rate of 15% per annum from March 31, 2026 until such Convertible Notes were converted in connection with the IPO. The Convertible Notes were subject to automatic conversion into shares of preferred stock issued in connection with a preferred stock financing of greater than $150.0 million (a "Qualified Financing"). Additionally, upon election of the holders of the Convertible Notes representing a majority of the loan amount outstanding (the "Requisite Noteholders"), the Convertible Notes were subject to conversion in connection with a financing transaction that is not a Qualified Financing. The conversion price was subject to a 10% discount to the price per share paid by investors purchasing shares with cash. If the Convertible Notes were not converted or repaid in full prior to the maturity date in September 2027, the Convertible Notes would have been subject to voluntary conversion into shares of our Series C-3 Preferred Stock, at the election of the Requisite Noteholders, at a price per share equal to approximately $14.98.

In March 2026, the Company amended the Convertible Notes to include a mandatory conversion feature upon the consummation of an IPO. In connection with the IPO, in lieu of repayment of the outstanding balance, the entire amount outstanding automatically converted at a conversion price equal to a 10% discount to the price per share at which the shares of common stock were sold to the public. The holders of the Convertible Notes could elect to receive all or a portion of the shares issuable to such holder in the form of a pre-funded warrant to purchase shares of the Company's common stock, solely so that the holder will beneficially own less than 20% of the Company's outstanding common stock immediately following the consummation of the IPO.

In August 2026, the Company completed its IPO resulting in the conversion of all outstanding Convertible Notes, including accrued interest, into 2,646,838 shares of common stock.

The Company elected to account for the Convertible Notes at fair value where changes in fair value are measured through the unaudited condensed consolidated statements of operations until settlement. The Company recorded a gain on the change in fair value of $1.3 million for the nine months ended September 30, 2026. The change in fair value of the Convertible Note during the three months ended September 30, 2026 was not considered material.

10. REVENUE - RELATED PARTY

As discussed in Note 4, upon formation of SASS, the Company entered into multiple agreements with SASS. Based on the nature of these agreements, the Company concluded that SASS represented a customer and analyzed the agreements between the Company and SASS in accordance with ASC 606. The Company entered into a limited liability agreement with SASS upon formation of the joint venture, granted SASS an exclusive license for intellectual property and know-how related to certain of the Company's sleep breathing disorder programs, excluding any rights to the Company's Oxnimbi and AD504 programs, and executed an MSA with SASS. The Company has combined these contracts for the purpose of identifying the underlying obligations as they were negotiated together with a single commercial objective, the purpose of conducting research and development activities to treat, prevent and mitigate OSA and other sleep breathing disorders, the amount of consideration to be paid in one contract depends on the performance of the other contract, the license and option for future services promised in the contracts are a single performance obligation.

The Company evaluated the promised goods and services under the agreements and determined that the agreements included one performance obligation: a combined performance obligation including the exclusive license, know-how and services to be performed under the MSA in accordance with SASS's research and development plan. These services will be contracted under statements of work between Apnimed and SASS. The Company concluded the promised goods and services represent one combined performance obligation given the highly specialized, proprietary approach and technology, as well as a scientific team with an extensive clinical background in sleep medicine that Apnimed is providing to SASS. The research and development services provided to SASS by Apnimed, under the MSA and Shionogi, under the Shionogi MSA with SASS, on the licenses and IP contributed to SASS are interrelated and interdependent as all are related to the main purpose of SASS which is research and development activities to treat, prevent, and mitigate OSA and other sleep breathing disorders. As such, the promised goods and services are not considered to be distinct within the context of the contract.

The transaction price was determined to be $75.0 million at the time of execution, which represented the fair value of the Company's equity interest in SASS as of the Closing Date, and as noted above in Note 4, the Company recorded the initial investment of $75.0 million on its consolidated balance sheet and also recorded $75.0 million as deferred revenue. The Company allocated the full transaction price to the combined performance obligation. The Company will recognize the $75.0 million as the Company fulfills its performance obligation to SASS using an input method based on expected costs incurred to provide the MSA services in accordance with SASS's research and development plan, which in management's judgment is the best measure of progress towards satisfying the performance obligation as this method provides the most faithful depiction of the entity's performance in transferring control of the goods and services promised to SASS. The Company expected to fulfill its performance obligation to SASS over five years, the initial term of the joint venture. The Company will re-evaluate the measure of progress in each reporting period or as new statements of work ("SOWs") are executed and, if necessary, adjust the measure of progress and related revenue recognition.

As discussed in Note 4, in April 2025, upon the execution of the Joint Ownership Agreement and the Contribution Agreement, the Company reclassified $14.7 million of the initial deposit liability recorded as of December 31, 2024 to deferred revenue using the relative fair value method relating to the Atomoxetine Licensed IP. The rights granted to SASS under the Contribution Agreement were recorded in accordance with ASC 606 and concluded to be modifications of the original SASS revenue arrangement, rather than a separate contract as the goods and services are not distinct from those identified in the original contract, resulting in an increased transaction price of $74.4 million, which is comprised of the value from the deposit liability allocated to the Atomoxetine Licensed IP of $14.7 million, the $22.5 million received from Shionogi allocated to the Atomoxetine Licensed IP, and the value of the Desitin IP recorded as an increase in equity method investment of $37.2 million as discussed in Note 4.

During the nine months ended September 30, 2026, the Company revised its estimate of the total expected costs to be incurred to provide the MSA services primarily due to the MIPA discussed in Note 4. As a result of the change in estimate, the measure of progress toward completion of the one performance obligation was adjusted in accordance with ASC 606 under the cumulative catch-up method. The change in accounting estimate resulted in an increase in revenue of $81.3 million, an increase in net income of $81.3 million, an increase in basic net income per share of $6.44 and an increase in diluted income per share of $4.81, in each case for the nine months ended September 30, 2026.

The transaction price was $171.6 million and $171.5 million as of September 30, 2026 and December 31, 2025, respectively.

During the nine months ended September 30, 2026, the Company recognized revenue of $99.4 million, of which $93.5 million was included in deferred revenue as of the beginning of 2026. During the nine months ended September 30, 2025, the Company recognized revenue of $29.0 million, of which $17.2 million was included in deferred revenue as of the beginning of 2025.

Deferred revenue was $17.3 million and $113.1 million as of September 30, 2026 and December 31, 2025, respectively.

11. CONVERTIBLE PREFERRED STOCK

The Company had issued and outstanding convertible Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series C-3 Preferred Stock, Series D Preferred Stock and Series D-1 Preferred Stock (together, the "Preferred Stock" and each series of the Preferred Stock, a "Series"). A summary of each Series outstanding immediately prior to the completion of the Company's IPO on August 3, 2026 is presented below (gross proceeds, net proceeds, and liquidation preference presented in thousands).

Series	Date	Issued and Outstanding	Price	Gross Proceeds	Net Proceeds	Liquidation Preference	Shares Authorized
Series A Preferred Stock	June 2018	942,685	$ 4.7736	$ 4,500	$ 4,177	$ 5,268	942,685
Series A Preferred Stock—conversion of outstanding note	June 2018	160,797	—	—	—	—	160,797
Series A Preferred Stock	July 2018	942,685	$ 4.7736	4,500	4,177	4,500	942,685
Series A Preferred Stock	January 2019	2,094,855	$ 4.7736	10,000	9,991	10,000	2,094,855
Series A Preferred Stock	August 2019	1,256,913	$ 4.7736	6,000	5,030	6,000	1,256,913
Series A-2 Preferred Stock	March 2020	2,349,108	$ 6.3854	15,000	14,903	15,000	2,349,108
Series B Preferred Stock	March 2021	2,818,964	$ 8.8685	25,000	24,862	25,000	2,818,964
Series C-1 Preferred Stock	April 2022	4,222,581	$ 8.8808	37,500	37,104	37,500	4,222,581
Series C-2 Preferred Stock	October 2022	2,252,042	$ 11.1010	25,000	24,957	25,000	2,252,042
Series C-3 Preferred Stock	December 2022	7,184,033	$ 11.1010	79,750	79,689	79,750	7,184,033
Series D Preferred Stock	April 2025	1,709,453	$ 9.6522	16,500	16,257	16,500	1,709,453
Series D-1 Preferred Stock	March 2026	2,587,991	$ 9.6600	25,000	24,792	25,000	3,623,187
		28,522,107		$ 248,750	$ 245,939	$ 249,518	29,557,303

Immediately prior to the completion of the IPO in August 2026, all outstanding shares of convertible Preferred Stock automatically converted into 21,143,116 shares of Class A Common Stock. Immediately thereafter, all outstanding shares of Class A Common Stock were reclassified and renamed into shares of common stock of the Company.

Significant provisions of the convertible Preferred Stock are as follows:

Rights, Preferences, Privileges and Restrictions—The shares of the convertible Preferred Stock have the following rights, preferences, privileges and restrictions:

Dividends—The holders of convertible Preferred Stock were entitled to receive non-cumulative and non-accruing dividends on an equal priority, in an amount at least equal to 8% of each Series' original issue price. Dividends were payable only when, as, and if declared by the Board of Directors of the Company. There have been no dividends declared or paid.

Voting Rights—Each holder of outstanding shares of convertible Preferred Stock was entitled to the number of votes equal to the number of whole shares of Class A Common Stock into which the shares of Preferred Stock were convertible. Except as provided by law or by the provisions of the Company's Eighth Amended and Restated Certificate of Incorporation ("Certificate of Incorporation"), holders of the convertible Preferred Stock would vote together with the holders of Class A Common Stock as a single class, and on an as converted basis.

The holders of record of the shares of Series A Preferred Stock, Series A-2 Preferred Stock and Series B Preferred Stock, exclusively and as a separate class, were entitled to elect one director of the Company. The holders of record of the shares of Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series C-3 Preferred Stock, exclusively and as a separate class, were entitled to elect two directors of the Company. Holders of record of the shares of Class A Common Stock, exclusively and as a separate class, were entitled to elect two directors of the Company. Holders of record of the shares of Class A Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, and on an as-converted basis, were entitled to elect three directors of the Company (for a total of eight directors on the Board).

Conversion—Each share of convertible Preferred Stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Class A Common Stock as is determined by dividing each Series' original issue price by each Series' conversion price in effect at the time of conversion. The original issue price and the conversion price of the Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series C-3 Preferred Stock, Series D Preferred Stock and Series D-1 Preferred Stock are $4.7736, $6.3854, $8.8685, $8.8808, $11.1010, $11.1010, $9.6522 and $9.6600, respectively. Such conversion prices, and the rate at which shares of Preferred Stock may have been converted into shares of Class A Common Stock, subject to adjustments, for occurrences such as stock splits and combinations, certain dividends and distributions and mergers or reorganizations.

All outstanding shares of convertible Preferred Stock would have automatically be converted into shares of Class A Common Stock, at the then effective conversion rate, upon the earlier of: (a) the closing of the sale of shares of Class A Common Stock to the public at a price of at least $19.77 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Class A Common Stock), in a firm-commitment underwritten public offering, resulting in at least $75.0 million of proceeds, or (b) the date and time, or the occurrence of an event, specified by a vote or written consent of at least 60% of the holders of shares of convertible Preferred Stock.

Liquidation—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, (i) the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series C-3 Preferred Stock would have been entitled to be paid out before any payment shall be made to the holders of common stock, an amount per share equal to one-times (1x) the applicable original issue price, plus any dividends declared but unpaid thereon and (ii) the holders of shares of Series D Preferred Stock and Series D-1 Preferred Stock would have been entitled to be paid out before any payment shall be made to the holders of common stock, an amount per share equal to the greater of (a) one times (1x) the Series D Preferred Stock or the Series D-1 Preferred Stock original issue price, as applicable, plus any dividends declared but unpaid thereon, or (b) such amount, if any, per share as would have been payable had all such shares of Series D Preferred Stock or Series D-1 Preferred Stock, as applicable, been converted into Class A Common Stock. After the payment in full of all amounts required to be paid to the holders of shares of convertible Preferred Stock, the remaining assets of the Company available for distribution to its stockholders would have been distributed among the holders of shares of common stock and convertible Preferred Stock.

In the event of (a) a merger or consolidation in which the Company is a constituent party or (b) the sale, lease, or transfer (or similar disposition) of all or substantially all of the Company's assets, a "Deemed Liquidation Event" would have been considered to have occurred. In the event of a Deemed Liquidation Event, if the Company did not effect a dissolution of the Company under Delaware law within sixty days after such Deemed Liquidation Event, then (i) the Company shall notify each holder of convertible Preferred Stock advising such holders of their right to require the redemption of their shares of convertible Preferred Stock, and (ii) the Company would have used the net consideration received by the Company for such Deemed Liquidation Event to redeem each outstanding share held by each holder of convertible Preferred Stock that elects to redeem its shares of convertible Preferred Stock at a price per share equal to the maximum amount per share of convertible Preferred Stock, as applicable, payable under the same procedure as described in the paragraph above.

Redemption Rights—Holders of convertible Preferred Stock were not entitled to any redemption rights other than those rights reserved in connection with a Deemed Liquidation Event.

On May 28, 2026, the Company filed a Certificate of Amendment to its 2026 Amendment (as defined in Note 12) to increase the total number of authorized shares of Preferred Stock to 29,557,303 shares.

12. STOCKHOLDERS' EQUITY

On March 11, 2026, the Company filed the Eighth Amended and Restated Certificate of Incorporation of the Company (the "2026 Amendment"), which increased the total authorized number of shares of Class A Common Stock. Pursuant to the 2026 Amendment, the total number of shares of all classes of Common Stock increased to 49,250,415, consisting of 46,105,170 shares of Class A Common Stock, 2,948,668 shares of Class B Common Stock, and 196,577 shares of Class C Common Stock.

On May 28, 2026, the Company filed a Certificate of Amendment to its 2026 Amendment to increase the number of authorized shares of Class A Common Stock. Following the amendment, the total authorized number of shares of all classes of Common Stock increased to 51,712,954 shares, consisting of 48,567,709 shares of Class A Common Stock, 2,948,668 shares of Class B Common Stock, and 196,577 shares of Class C Common Stock.

In August 2026 the Company amended and restated its certificate of incorporation, pursuant to which the Company is authorized to issue 500,000,000 shares of $0.00001 par value common stock and 10,000,000 shares of preferred stock, par value $0.00001 per share. Holders of common stock are entitled to one vote per share and are entitled to receive dividends when and if declared by the Company's board of directors. Upon liquidation, dissolution, or winding up of the Company, holders of common stock are entitled to share ratably in the Company's net assets remaining after payment of liabilities and any preferential rights of outstanding preferred stock. The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preference of the holders of any preferred stock then issued and outstanding.

In August 2026, in connection with the IPO, all outstanding shares of the Company's Class B and Class C common stock were automatically converted into 2,040,097 and 145,720 shares of the Company's Class A common stock, respectively. Immediately thereafter, all outstanding shares of the Company's Class A common stock were reclassified as shares of Common Stock.

As of September 30, 2026, the Company has reserved the following shares of common stock for future issuance:

	September 30, 2026
Outstanding options to purchase common stock	10,914,655
Warrants (defined in Note 16)	100,163
	11,014,818

13. STOCK-BASED COMPENSATION

In July 2017, the Company's board of directors adopted the 2017 Stock Incentive Plan (“2017 Plan”), which provides for the issuance of incentive awards and restricted share awards to employees, officers, directors, advisors, and outside consultants for the purchase of up to 600,000 shares of common stock. The 2017 Plan was subsequently amended from time to time, most recently in June 2026, to increase the availability for the issuance of awards up to 12,774,442 shares of common stock.

The options granted generally vest over 48 months. Certain stock options provide for accelerated vesting on a change in control, as defined in the respective agreement. The 2026 Stock Option and Incentive Plan ("2026 Plan") became effective upon the effectiveness of the IPO. Upon the effectiveness of the 2026 Plan, the Company ceased granting awards under the 2017 Plan.

The 2026 Plan authorizes the award of both equity-based and cash-based incentive awards, including (i) options (both incentive stock options and nonqualified stock options), (ii) stock appreciation rights ("SARs"), (iii) restricted stock awards ("RSAs"), (iv) restricted stock units ("RSUs") and (v) cash or other stock-based awards. Incentive stock options may be granted only to employees. All other types of awards may be issued to employees, directors, consultants and other service providers. The total awards available for issuance under the 2026 Plan include up to 5,811,181 shares of common stock. As of September 30, 2026, 4,628,503 shares were available for issuance under the 2026 Plan.

During the three months ended September 30, 2026, the Company modified the terms of certain previously granted stock-based awards held by former employees, including accelerating the vesting of certain unvested awards and extending the post-termination exercise period of certain vested awards. The Company accounts for modifications in accordance with ASC 718, Compensation—Stock Compensation, and recognizes any incremental compensation cost resulting from a modification. The Company recognized incremental stock-based compensation expense of $3.1 million for the three months ended September 30, 2026 as a result of these modifications, which was primarily recorded in general and administrative expense.

The following table summarizes the stock option activity during the nine months ended September 30, 2026:

	Options and Awards Outstanding	Weighted-Average Exercise Price	Weighted-Average Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2026	6,820,263	$ 3.85	6.14	$ 63,652
Granted	4,441,989	12.27		
Exercised	(22,420)	3.50		214
Expired/Forfeited	(325,177)	4.35		
Outstanding at September 30, 2026	10,914,655	$ 7.24	7.15	$ 160,069
Options exercisable at September 30, 2026	6,233,447	$ 3.85	4.68	$ 112,588
Vested and expected to vest at September 30, 2026	10,914,655	$ 7.24	7.15	$ 160,069

The weighted-average grant date fair value of the options granted during the nine months ended September 30, 2026 was $12.39.

The key assumptions used in determining the fair value of equity awards, and the Company’s rationale, were as follows: (i) *Expected term* - the expected term for stock options represents the period that the stock options are expected to be outstanding and has been estimated using the simplified method, due to limited historical exercise behavior. The expected term using the simplified method is an average of the contractual option term and its vesting period; (ii) *Expected volatility* - the expected volatility assumption was based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available. The Company computed the historical volatility data using the daily closing prices for the selected companies’ shares during the period equivalent to the expected term of the Company’s stock-based awards; (iii) *Risk-free interest rate* - the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities that approximate the expected terms of awards; (iv) *Exercise price* - Following the IPO, the exercise price of stock options granted is equal to the closing price of our common stock on the date of grant. Prior to the IPO, the exercise price of stock options granted was based on the valuation methods consistent with the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation.* Key inputs included market conditions, the prices of convertible preferred share sales, the preferred shares’ senior rights and the probabilities of liquidity events such as an IPO or a sale; and (v)

Expected dividend yield - the expected dividend yield assumption is zero as the Company has never paid dividends and has no present intention to do so in the future.

Unrecognized stock-based compensation expense related to unvested stock options was approximately $40.77 million as of September 30, 2026, to be recognized over a weighted average period of 3.03 years.

Employee Stock Purchase Plan—In connection with the IPO, the Board approved the reservation of 558,767 shares of common stock for a future Employee Stock Purchase Plan ("ESPP"). Under the ESPP, employees have an opportunity to purchase shares of the Company's common stock at a discounted purchase price. The ESPP is intended to qualify as an "employee stock purchase plan" meeting the requirements of Section 423 of the Internal Revenue Code of 1986.

As of September 30, 2026, the ESPP had not been formally activated and no shares were issued or purchased thereunder.

Inducement Plan—In August 2026, the Company's board of directors adopted and approved the 2026 Inducement Plan ("Inducement Plan") and reserved 2,500,000 shares of the Company's common stock to be used exclusively for grants of awards to individuals not previously employed by the Company, as a material inducement to such individuals' entry into employment with the Company within the meaning of Nasdaq Listing Rule 5635(c)(4). Under the Inducement Plan, the Company may grant these eligible recipients nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and other equity-based awards.

As of September 30, 2026, options to purchase 428,428 shares of common stock were granted to new employees under the Inducement Plan.

Stock-Based Compensation Expense—The Company recognized the following compensation cost related to employee and non-employee stock-based compensation activity for the periods presented below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 991	$ 352	$ 1,733	$ 1,025
General and administrative	5,282	874	6,660	1,869
Total	$ 6,273	$ 1,226	$ 8,393	$ 2,894

14. SEGMENT DATA

The Company defines its segments on the basis of the way in which internally reported financial information is regularly reviewed by the chief operating decision maker ("CODM"), to analyze financial performance, make decisions, and allocate resources. The Company's CODM is its Chief Executive Officer. The Company manages its operations as a single operating and reportable segment dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases. The CODM uses net income (loss) to monitor budget versus actual results and to analyze cash flows in assessing performance of the segment and allocating resources. All business activities are managed on a consolidated basis. As discussed further in Note 10, all revenue - related party recognized during the period has been generated from the SASS joint venture with Shionogi, which includes a combined performance obligation including the exclusive license under the Company's license agreement with SASS, which the Company entered in November 2023, and services to be performed under the MSA in accordance with SASS's research and development plan. The internal reporting of significant segment expenses is based on functional classification. The measure of the operating segment assets is reported on the consolidated balance sheet as total assets. All tangible assets and operations of the Company's sole operating segment are located in the United States.

The following table sets forth the details within the Company's segment, including significant expenses, certain other segment expenses, and a reconciliation to net income (loss) (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue - related party	$ 2,480	$ 8,802	$ 99,374	$ 29,043
Research and development expenses				
Oxnimbi	2,517	4,495	8,037	29,981
Connected wearables	219	222	783	812
Medical affairs	2,709	618	5,494	3,666
Other projects	7	14	29	821
Employee related expenses	5,369	4,053	13,740	12,874
General and administrative expenses				
General and administrative	12,191	4,059	23,879	12,299
Commercial marketing	5,155	1,112	11,269	2,700
Stock-based compensation	6,273	1,226	8,393	2,894
Cost of services - related party	245	1,987	3,615	5,028
Interest income	1,814	263	3,002	1,003
Gain on reversal of deposit liability	—	—	57,120	—
Change in fair value of long-term debt	1,208	—	(451)	—
Change in fair value of revenue interest liability	(260)	—	(720)	—
Change in fair value of convertible notes	—	—	1,315	—
Other expense	(81)	—	(2,819)	—
Loss from discontinued operations	—	(2,189)	(2,832)	(68,001)
Gain on sale of equity method investment, discontinued operations	—	—	85,380	—
Net income (loss)	$ (29,524)	$ (10,910)	$ 164,130	$ (109,030)

Other projects consist of research and development costs related to certain earlier stage sleep and breathing disease programs. General and administrative expenses include items related to personnel, including bonus and benefit related expenses, legal and professional services, rent and utilities, general consulting services and other office-related expenses.

15. DISCONTINUED OPERATIONS

On March 23, 2026, the Company entered into a definitive agreement, and in April 2026, the Company completed the disposition of its 50% interest in SASS to Shionogi pursuant to the MIPA, as discussed in Note 4. The Company has historically accounted for its interest in SASS under the equity method of accounting as discussed in Note 4.

The SASS divestiture represents a strategic monetization of the Company's interest in SASS as it focuses on the advancement and planned commercialization of Oxnimbi. The Company determined that the divestiture represents a strategic shift that has had, or will have, a major effect on the Company's operations and financial results. Accordingly, the results of SASS have been classified as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*.

As of March 31, 2026, the Company concluded that its investment in SASS met the criteria for classification as held for sale. As a result, the Company recast $26.9 million related to its equity method investment as assets held for sale in its consolidated balance sheet as of December 31, 2025.

The Company recorded income on its equity method investments of $0.0 million and $82.5 million within income from discontinued operations for the three and nine months ended September 30, 2026, respectively. In addition, the Company recast $2.2 million and $68.0 million related to its loss on equity method investments to loss from discontinued operations in its unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2025, respectively.

Following the divestiture, the Company expects to have continuing involvement with SASS through the MSA (Note 10), as amended to date, under which the Company continues to perform research and development services under the single, combined performance obligation. The Company expects these services to be substantially complete within one year from the completed disposition. The performance of these services does not allow the Company to regain significant influence or control of SASS and the

Company does not have the power to solely direct the activities of SASS that most significantly impact SASS's economic performance, as the Company no longer has any ownership or representation on SASS's board of managers.

Refer to Note 4 for additional information regarding the completion of disposition of SASS.

16. CREDIT AGREEMENT

On April 2, 2026, the Company entered into a term loan facility (the "Credit Agreement") with HCRx Investments HoldCo, L.P., HCR Stafford Fund II, L.P. and HCR Potomac Fund II, L.P (collectively, the "Lenders") and HCR OSA SPV, LLC, as administrative agent and collateral agent (the "Agent"). The Credit Agreement provides for up to $150.0 million of term loans (the Term Loans), available to us in multiple tranches. On April 2, 2026, the Lenders advanced $50.0 million of term loans (the "Tranche A Term Loan") to the Company. The maturity date of the Tranche A Term Loan is April 2, 2031. Additionally, the Company will be entitled to receive an advance of $50.0 million (the "Tranche B Term Loan") upon receipt of regulatory authorization from the FDA for Oxnimbi with a labeled indication for the treatment of OSA in any adult population (the "Tranche B Milestone Event") and an additional advance of $50.0 million (the "Tranche C Term Loan") if, on or prior to June 30, 2028, the trailing twelve-month net sales of the products covered by the BWH License equals or exceeds $175.0 million (the "Tranche C Milestone Event"), both upon agreement between the Company and the Lenders.

Outstanding Term Loans accrue interest at an annual rate equal to Three-Month Term SOFR (as defined in the Credit Agreement) plus 5.75%, subject to potential reductions of up to one percent upon completion of certain events specified in the Credit Agreement (the "Credit Agreement Interest Rate"). Until April 2, 2027, the Company may elect, subject to certain conditions specified in the Credit Agreement, to pay 100% of accrued interest in-kind by capitalizing such interest into principal subject to an interest rate increase of 0.75%. In addition to interest on the outstanding Term Loans, the Company agreed to pay a revenue interest (the "Revenue Interest") on each quarterly payment date, beginning May 15, 2026, calculated as a percentage of the Company's net revenues equal to a low single digit percentage on the portion of annual net revenues up to $200.0 million and an amount below one percent on the portion of annual net revenues between $200.0 million and $500.0 million, in each case until the earlier of the ten-year anniversary of the first commercial sale of Oxnimbi or earlier extinguishment pursuant to the terms of the Credit Agreement. The Company assessed the accounting for the Revenue Interest and identified it as a sale of future revenue in the form of a debt instrument to be accounted for as debt under ASC 470.

The Company can voluntarily prepay the Term Loans from time to time, in whole and in part, and is required to prepay the Term Loans upon receipt of proceeds from certain asset sales, extraordinary receipts and debt incurrences, subject, in each case, to certain exceptions set forth in the Credit Agreement. All prepayments (other than prepayments upon a change of control as such term is defined in the Credit Agreement) are subject to a prepayment premium equal to a make-whole amount (reflective of all interest that would have accrued on such prepaid amount from April 2, 2026 to April 2, 2028) plus 5.0% if made on or prior to April 2, 2028, 4.00% if made after April 2, 2028 and on or prior to April 2, 2029, 2.50% if made after April 2, 2029 and on or prior to April 30, 2029, and 0.00% thereafter. Mandatory prepayments are required from net cash proceeds from dispositions, involuntary dispositions, extraordinary receipts and debt issuances. In addition, upon any prepayment or repayment (other than in connection with a change of control), the Company is required to pay a final payment premium equal to 4.0% of the portion of the applicable Term Loan amount being repaid.

The Credit Agreement contains various affirmative and negative covenants, which are subject to customary exceptions, that limit the Company's ability to engage in specified types of transactions without the prior written consent of the Lenders. In addition, the Company is required to deposit into controlled accounts all cash or other payments received with respect to any and all of its accounts receivable or any other contract or right and interest and, at all times, to maintain a minimum aggregate balance of $20.0 million in cash in one or more such controlled accounts. These accounts are required to be maintained as cash collateral accounts securing the Company's obligations under the Credit Agreement.

In connection with the Credit Agreement, the Company issued warrants to purchase an aggregate of 100,163 shares of the Company’s Class A common stock to the Lenders (the “Warrants”). The Warrants may be exercised at any time after the date of issuance through either a nominal cash payment or a cashless exercise, at the holder’s election, until April 2, 2036. Additionally, pursuant to the Credit Agreement, the Company is obligated to issue Warrants to Lenders as a condition to the Lenders’ obligation to advance the Tranche B Term Loan and the Tranche C Term Loan to the Company. The Warrants were determined to be freestanding financial instruments and meet the criteria for permanent equity classification. As of September 30, 2026, Warrants to purchase 100,163 shares of the Company's common stock were outstanding and a total value of $0.8 million was recorded within additional paid-in capital net of issuance costs.

The Company evaluated the accounting for the Credit Agreement and identified multiple freestanding financial instruments. The total proceeds received of $49.0 million were allocated utilizing the with or without method at issuance date. The Company elected to account for certain of these freestanding financial instruments at fair value where changes in fair value are measured through the unaudited condensed consolidated statements of operations until settlement. The initial fair values of the Tranche A Term Loan and Revenue Interest were $38.6 million and $9.6 million, respectively, with the residual allocated to the Warrants. The Company

recorded a loss on the change in fair value of Tranche A Term Loan and Revenue Interest of $0.5 million and $0.7 million, respectively, in other expense during the nine months ended September 30, 2026, and a gain of $1.2 million and loss of $0.3 million related to the estimated fair value of the Tranche A Term Loan and Revenue Interest liability, respectively during the three months ended September 30, 2026. The Company recorded the Tranche A Term Loan and Revenue Interest at their estimated fair value of $39.1 million and $10.3 million, respectively, as long-term liabilities on its unaudited condensed consolidated balance sheet as of September 30, 2026. The Company incurred issuance costs of $2.9 million, which were expensed as incurred.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes included in our final prospectus for our initial public offering ("IPO") filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b)(4) under the Securities Act on July 31, 2026 (the "IPO Prospectus"). References to the "Company," "Apnimed," "we," "our," "us" or similar terms refer to Apnimed, Inc. as the context may require. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report. The sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" should be read carefully to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a late-stage clinical pharmaceutical company dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases. Our clinical product candidate, AD109 with a proposed proprietary name Oxnimbi™ (aroxybutynin and atomoxetine) tablets, for oral use ("Oxnimbi"), is an investigational, fixed-dose anti-apneic neuromuscular modulator, combining a novel anti-muscarinic and a selective norepinephrine reuptake inhibitor ("NRI") for the treatment of obstructive sleep apnea ("OSA") in adults. Oxnimbi is designed to target the neuromuscular defect of OSA by improving upper airway muscle activity to help maintain airway patency and prevent airway collapse during sleep. Based on results from two registrational trials, we submitted a New Drug Application ("NDA") for AD109 to the FDA in April 2026, which was accepted for review by the FDA in July 2026. The registrational trials, LunAIRo and SynAIRgy, were Phase 3 randomized, double-blind, placebo-controlled, parallel-arm trials in adults with mild to severe OSA, which together enrolled approximately 1,300 patients and represent one of the largest and most diverse cohorts ever studied in an OSA pharmacologic trial. LunAIRo was conducted in the United States and SynAIRgy was conducted in the United States and Canada. All other trials for AD109 were conducted in the United States.

AD109 met its primary endpoint and several key secondary endpoints in both Phase 3 trials, SynAIRgy and LunAIRo. Under the treatment policy estimand, mean apnea hypopnea index reductions at week 26 (≥4% (desaturation criterion for hypopneas) were 44.1% in SynAIRgy and 33.7% in LunAIRo vs 17.6% and 7.3% with placebo, respectively ($p \leq 0.0001$). Under the on-treatment estimand, reductions were 55.6% and 46.8% from baseline vs 19.1% and 6.8% with placebo, respectively ($p < 0.0001$ vs placebo). Under the treatment policy estimand, hypoxic burden, a metric associated with cardiovascular risk and all-cause mortality, was reduced by 44.7% and 37.4% from baseline vs 8.5% and 10.0% with placebo ($p < 0.001$ vs placebo), and under the on-treatment estimand by 60.5% and 58.2% vs 14.7% and 13.8% with placebo ($p < 0.0001$ vs placebo), in SynAIRgy and LunAIRo, respectively. AD109 was generally well-tolerated, with AEs predominantly mild across both trials, with no drug-related serious adverse events in the AD109 group reported in either LunAIRo or SynAIRgy. Clinical trial results are preliminary in nature, and such results may not be replicated in subsequent clinical trials. The FDA review cycle is targeted to be 10 months from our NDA submission in April 2026, and the FDA has issued a Prescription Drug User Fee Act ("PDUFA") goal date of February 28, 2027, although the duration of the review may vary based on various factors.

In addition, we entered into a joint venture with Shionogi & Co., Ltd. ("Shionogi"), known as Shionogi-Apnimed Sleep Science, LLC ("SASS"), to develop novel therapies for OSA and other sleep breathing disorders in November 2023. SASS initiated several discovery and development-stage programs in 2024 and continued development in 2025.

In April 2026, we completed the SASS Disposition, in which we sold to Shionogi (i) all of our membership interests in SASS and (ii) certain intellectual property and other assets directly related to SASS's development programs, including the asset purchase and license agreement (the "Desitin APA") with Desitin Arzneimittel GmbH ("Desitin") and Cereus Pharma AB ("Cereus"), pursuant to the Membership Interest and Asset Purchase Agreement (the "MIPA") with Shionogi and SASS, dated March 23, 2026, as amended (the "SASS Disposition"). In addition, at the closing of the SASS Disposition, we converted certain exclusive licenses to our intellectual property relevant to the use of compounds in sleep disorders that were within the scope of SASS's pre-closing activities (each, a "JV Compound") and in existence as of the effective date of the MIPA into perpetual, irrevocable, non-exclusive and royalty-free licenses solely with respect to a specified set of products that incorporate one or more JV Compound. As partial consideration under the MIPA, we received an upfront payment of $100.0 million (the "Closing Payment"). In addition, we are eligible to receive a one-time milestone payment of $50.0 million (the "Milestone Payment") subject to the earlier achievement of (i) the first subject being enrolled into the second clinical trial of a sulthiame product sponsored by Shionogi, SASS or either of their licensees, sublicensees, or affiliates (each an "Earnout Party" and collectively, the "Earnout Parties") (the "MIPA Clinical Development Milestone") and (ii) FDA acceptance of an NDA for a sulthiame product submitted by an Earnout Party (the "MIPA Regulatory Milestone").

In August 2026, we completed our IPO, in which we sold an aggregate of 13,800,000 shares of our common stock, including 1,800,000 shares issued pursuant to the full exercise of the underwriters' overallotment option, at a public offering price of $16.00 per

share, resulting in aggregate net proceeds of approximately $198.9 million, after deducting underwriting discounts, commissions and other offering expenses.

We have a history of operating losses and, prior to our IPO, we had limited capital resources. In addition, as of September 30, 2026, we had an accumulated deficit of $233.2 million and had cash and cash equivalents of $351.8 million. For the nine months ended September 30, 2026 and 2025, we used $59.1 million and $63.1 million of cash in operations, respectively. We expect to continue to generate operating losses and negative cash flows for the foreseeable future as we continue to develop Oxnimbi and any future product candidates.

We believe that our cash and cash equivalents as of September 30, 2026, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. However, our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. See the sections titled "Liquidity and Capital Resources" below and "Risk Factors—Risks Related to Our Operating History, Financial Condition and Need for Additional Capital" included elsewhere in this Quarterly Report.

We do not expect to generate any revenue from commercial product sales unless we successfully complete development and obtain regulatory approval for Oxnimbi or any future product candidate, which may never occur. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue to seek regulatory approval, and pursue indication expansion of Oxnimbi;
- establish a sales, marketing and distribution infrastructure to commercialize Oxnimbi or any future product candidates for which we may obtain regulatory approval;
- establish and expand manufacturing capabilities and supply chain capacity for Oxnimbi or any future product candidates;
- seek to identify additional research programs and program candidates to build a pipeline;
- initiate and complete additional nonclinical studies and clinical trials of Oxnimbi, if required, or any future product candidates and seek regulatory approvals for Oxnimbi or any future product candidates for which we successfully complete clinical trials;
- hire additional research and development, clinical, commercial and operational personnel;
- experience any delays, challenges or other issues associated with any of the above, including the failure of clinical trials meeting endpoints, the generation of unanticipated nonclinical study results or clinical trial data subject to differing interpretations or the occurrence of potential safety issues or other development or regulatory challenges;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- acquire or in-license product candidates, intellectual property and technologies;
- make royalty, milestone, or other payments under current and any future in-license purchase, collaboration or assignment agreements;
- establish and maintain collaborations; and
- incur additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and SEC requirements, director and officer insurance premiums, and stockholder relations costs.

In addition, if we obtain regulatory approval for Oxnimbi or any future product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. If Oxnimbi is approved, the earliest we would expect to generate revenue from product sales is 2027. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

Our net losses may fluctuate significantly quarter-to-quarter and year-to-year depending on commercialization progress of Oxnimbi, if approved, as well as the timing of our clinical trials and our expenditures on other research and development activities.

Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve profitability, and unless and until we are able to develop and commercialize Oxnimbi or any future product candidates, we will need to continue to raise additional capital. Even if we generate revenue from product sales, we expect to finance our operations through a combination of public or private equity offerings, debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. See the section titled “Liquidity and Capital Resources” below.

Key Components of Our Operating Results

Revenue - Related Party

In accordance with FASB ASC Topic 606, *Revenue from Contracts with Customers* and its related amendments (collectively known as “ASC 606”), we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized, for agreements within the scope of ASC 606, we perform the following five steps: (i) identification of the contract with the customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the separate performance obligations in the contract; and (v) recognize revenue associated with performance obligations as they are satisfied. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer.

As discussed in Notes 4 and 10 to our unaudited condensed consolidated financial statements, upon formation of SASS, we entered into multiple agreements with SASS. Based on the nature of these agreements, we concluded that SASS represented a customer and analyzed the agreements between us and SASS in accordance with ASC 606. We evaluated the promised goods and services under the agreements and determined that the agreements included one performance obligation: a combined performance obligation including the exclusive license, know-how and services to be performed under the Master Services Agreement we entered into with SASS in November 2023, as amended in January 2025 (the "SASS MSA") in accordance with SASS’s research and development plan. We recognized revenue as we fulfilled performance obligations based on an input method of expected costs incurred in accordance with SASS’s research and development plan.

The transaction price associated with the formation of SASS was determined to be $75.0 million at the time of execution, which represented the fair value of our equity interest in SASS as of the closing date of the transaction. We allocated the full transaction price to the combined performance obligation and recorded $75.0 million as deferred revenue. As we fulfilled our performance obligation to SASS, we used an input method based on expected costs incurred to provide the services under the SASS MSA in accordance with SASS’s research and development plan, which we believe was the best measure of progress towards satisfying the performance obligations as this method provides the most faithful depiction of the entity’s performance in transferring control of the goods and services promised to SASS.

In April 2025, we entered into a joint ownership and license agreement with Shionogi (the "Joint Ownership Agreement"), pursuant to which Shionogi obtained a joint interest in the Joint Ownership IP (as defined below in the section titled “Loss from Discontinued Operations”).

In April 2025, in connection with entering the Joint Ownership Agreement, we entered into the SASS CAI and SNRI/CAI Contribution Agreement (the "Contribution Agreement") with Shionogi and SASS, pursuant to which we and Shionogi granted to SASS an exclusive license of the Joint Ownership IP subject to the Joint Ownership Agreement. SASS agreed to use the Joint Ownership IP only for the conduct of each program, in accordance with the terms of the Amended and Restated Limited Liability Company Agreement dated November 1, 2023, as amended by Amendment No. 1 to Amended and Restated Limited Liability Company Agreement, dated April 23, 2025 (the "JV Agreement") and for the research, development and commercialization of the Joint Ownership IP. The Contribution Agreement was recorded as a contract modification of the original SASS revenue arrangement discussed further in Note 10 to our unaudited consolidated financial statements. The modified contract comprises one performance obligation in accordance with ASC 606 as described in Note 10 to our unaudited consolidated financial statements.

During the nine months ended September 30, 2026, we revised our estimate of the total expected costs to be incurred to provide the services pursuant to the SASS MSA, as amended, primarily due to entering into the MIPA, discussed in Note 15 to our unaudited condensed consolidated financial statements. As a result of the change in estimate, the measure of progress toward completion of the one performance obligation was adjusted in accordance with ASC 606 under the cumulative catch-up method. The change in accounting estimate resulted in an increase in revenue of $81.3 million, an increase in net income of $81.3 million, an increase in basic net income per share of $6.44, and an increase in diluted net income per share of $4.81, in each case for the nine months ended September 30, 2026.

During the nine months ended September 30, 2026, we recognized revenue of $99.4 million, of which $93.5 million was included in deferred revenue as of the beginning of 2026. During the nine months ended September 30, 2025, we recognized revenue of $29.0 million, of which $17.2 million was included in deferred revenue as of the beginning of 2025.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our research and discovery efforts and the development of Oxnimbi or any future product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), as well as consultants who conduct our clinical trials, preclinical studies and other scientific development services;
- costs related to acquiring, developing, and manufacturing clinical study material for our preclinical studies and clinical trials, including fees paid to contract manufacturing organizations ("CMOs");
- laboratory supplies and research materials;
- upfront, milestone and maintenance fees incurred under license, collaboration and other third-party agreements;
- costs related to compliance with clinical regulatory requirements; and
- research and development personnel costs including salaries, bonuses, benefits and stock-based compensation.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and clinical sites and analyzing the progress of clinical trials or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

External costs include fees paid to consultants, contractors and vendors, including CMOs and CROs, in connection with our clinical activities. We do not track our internal research and development costs on a program-by-program basis.

The successful development of Oxnimbi or any future product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of Oxnimbi or any future product candidates, due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of Oxnimbi or any future product candidates, if approved.

The duration, cost and timing of the clinical development of Oxnimbi or any future product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the initiation, type, scope, rate of progress and expenses of our ongoing research activities, as well as any preclinical studies and clinical trials and other research and development activities;
- the initiation, type, number and scope of clinical programs we decide to pursue;
- the uncertainties in clinical trial design and patient enrollment rates;
- the drop-out or discontinuation rates of clinical trial patients;
- establishing an appropriate safety and efficacy profile;
- successful enrollment in and completion of clinical trials;
- the timing, receipt and terms of marketing approvals from applicable regulatory authorities, if and when approved;
- making arrangements with third-party CMOs for manufacturing, the costs and timing of manufacturing, including as a result of inflation, any supply chain issues or component shortages;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for Oxnimbi and any future product candidates;
- our ability to not infringe, misappropriate or otherwise violate third-party intellectual property rights;
- commercializing Oxnimbi or any future product candidates, if approved, whether alone or in collaboration with others;

- continued acceptable safety profile of products following any regulatory approval; and
- potential additional safety monitoring requested by regulatory agencies.

A change in the outcome of any of these variables with respect to the development of Oxnimbi or any future product candidates would significantly change the costs and timing associated with the development of such product candidates. We may never obtain regulatory approval for Oxnimbi or any future product candidates. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of any future product candidates, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or for other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for Oxnimbi or any future product candidates, and, even if we do, successful commercialization of any approved product candidates may take several years and we expect to incur significant development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and employee-related costs for our finance, human resources and other administrative personnel, including salaries, benefits and other related costs, as well as expenses for outside professional services, including legal, accounting and audit services and other consulting fees, rent expense, other general administrative expenses and stock-based compensation.

We expect our general and administrative expenses will increase in the future in connection with increasing our headcount to support our potential commercialization efforts, building a commercial organization and sales and marketing team, and increasing costs as a result of being a public company. These increases will likely include additional costs related to the hiring of new personnel, including higher stock-based compensation expenses, and fees to outside consultants, as well as other expenses. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as stockholder and public relations expenses associated with operating as a public company.

Cost of Services - Related Party

Cost of services consisted of our costs to provide services for drug discovery required under performance obligations with SASS. These costs primarily included materials costs, service hours performed by our employees and costs from third-party CROs and service providers. During the nine months ended September 30, 2026 and 2025 we recognized cost of services to SASS of $3.6 million and $5.0 million, respectively. These pass through costs consisted of expenses incurred under the SASS MSA and were reimbursed to us on a monthly basis and included both third party vendor services and services performed by our employees, which were reimbursed on an agreed upon hourly rate as outlined in the SASS MSA, which approximates actual personnel costs incurred.

In April 2026, we amended and restated the SASS MSA (the "A&R SASS MSA") to reflect the change in relationship under the MIPA, pursuant to which we will continue to perform certain services for SASS under existing statements of work ("SOWs") through 2026 and certain other services through 2027, each at mutually agreed rates pursuant to the A&R SASS MSA.

Other Income (Expense)

Other income (expense) consists of interest income received on our cash equivalents, gain on reversal of deposit liability, changes in fair value of our long-term debt, revenue interest liability, contingent asset and convertible notes, and realized gains and losses on foreign currency transactions.

Income (Loss) from Discontinued Operations

Income (loss) from discontinued operations represents our share of the income (losses) recorded by SASS and our gain on sale of our equity method investment. In April 2026, we completed the disposition of our equity method investment in SASS pursuant to the MIPA discussed in Note 15 to our unaudited condensed consolidated financial statements. The divestiture represents a strategic monetization of our investment in SASS as we focus on the advancement and potential commercialization of Oxnimbi. For the nine months ended September 30, 2026 and 2025, we recorded income from discontinued operations of $82.5 million and a loss from discontinued operations of $68.0 million, respectively, within the unaudited condensed consolidated statements of operations.

Desitin APA

In April 2025, we entered into the Desitin APA with Desitin and Cereus, pursuant to which we (i) purchased certain patents and know-how related to sulthiame (the "Purchased Sulthiame IP") and (ii) obtained a perpetual, irrevocable exclusive, and fully paid-up

license to know-how controlled by Desitin concerning the manufacturing of products using sulthiame in the field of diagnosis, prevention, treatment, mitigation or control of sleep apnea and all other sleep diseases, disorders and conditions in humans including obesity hypoventilation syndrome (the "Licensed Sulthiame IP") in exchange for an upfront cash consideration of $50.0 million, (collectively the "Desitin IP"). In April 2026, we completed the SASS Disposition pursuant to the MIPA and concurrently all of our rights and obligations under the Desitin APA were transferred to Shionogi.

Shionogi Agreements

In November 2023, we entered into the Right of First Negotiation Agreement with Shionogi (the "ROFN Agreement"). Pursuant to the ROFN Agreement, we granted Shionogi a right of first negotiation over certain of our development candidates in return for a lump sum cash payment equal to $37.5 million. Oxnimbi was not subject to the restrictions of the ROFN Agreement. In evaluating the nature of the ROFN Agreement under ASC 606, we concluded the ROFN Agreement did not represent a contract with a customer because we were not legally or contractually obligated to transfer any goods or services at the time the ROFN Agreement was signed. Therefore, the cash consideration received upon signing the ROFN Agreement was recognized as a deposit liability. The deposit liability recognized represented our obligation to transfer either goods or services in the future if an agreement was executed. The deposit liability was expected to be recognized as revenue in future periods only if an ASC 606 contract was entered. As of December 31, 2025, the deposit liability totaled $57.1 million. In April 2026, the ROFN Agreement was terminated. The termination of the ROFN Agreement was completed without entering into a customer contract in accordance with ASC 606. As no revenue generating arrangement was made related to the remaining rights under the ROFN Agreement prior to its termination, and we do not have any future negotiation obligation upon the termination of the ROFN Agreement, the deposit liability of $57.1 million was derecognized and recorded as gain on reversal of deposit liability in April 2026.

In July 2024, Shionogi exercised its ROFN with respect to certain intellectual property covered under the ROFN Agreement (the "Optioned Selective NRI/CAI IP"). Negotiations ensued pursuant to the exercise of such right of first negotiation with respect to the Optioned Selective NRI/CAI IP. In April 2025, we entered into the Desitin APA. In April 2025, we and Shionogi also entered into the Joint Ownership Agreement and the Contribution Agreement. Shionogi paid us $55.0 million upon execution of the Joint Ownership Agreement.

Pursuant to the Joint Ownership Agreement, in April 2025, we granted to Shionogi (i) a 50% joint ownership interest in the Purchased Sulthiame IP, (ii) a co-exclusive license under the Licensed Sulthiame IP and (iii) a co-exclusive license under certain intellectual property in respect of the compound atomoxetine (Atomoxetine Licensed IP, and together with the intellectual property described in subsections (i) and (ii), the "Joint Ownership IP"). In addition to rights in the Joint Ownership IP, Shionogi was granted an exclusive right, exercisable at any time during the term of the Contribution Agreement to negotiate for additional rights over the Joint Ownership IP controlled by SASS to develop, manufacture or commercialize a product in Japan, South Korea, and Taiwan and the People’s Republic of China (the "Shionogi Option"). Shionogi paid us $55.0 million upon execution of the Joint Ownership Agreement.

Pursuant to the Contribution Agreement, we and Shionogi contributed the intellectual property subject to the Joint Ownership Agreement to SASS and in exchange the milestone payments and the earnout payments due pursuant to the Desitin APA were assigned to SASS.

The accounting for the Desitin APA, the ROFN Agreement exercise, the Joint Ownership Agreement and the Contribution Agreement, collectively, within the audited consolidated financial statements as of and for the year ended December 31, 2025 was as follows:

- Upon executing the Joint Ownership Agreement in April 2025, we received $55.0 million from Shionogi. We allocated $25.0 million to the Desitin IP and allocated the remaining $30.0 million between the Shionogi Option and the fair value of Shionogi’s 50% share of the Atomoxetine Licensed IP, representing $7.5 million and $22.5 million, respectively. The Shionogi Option was recorded as a deposit liability (see Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report) and the fair value of the Atomoxetine Licensed IP was recorded as deferred revenue (see Note 10 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report).
- The Desitin IP was not within the scope of ASC 730, *Research and Development* ("ASC 730") as it was purchased with the intent to be immediately contributed to SASS. As Shionogi purchased 50% of the rights over the Desitin IP, our contribution of the Desitin IP to SASS resulted in an increase to the equity method investment in SASS of $25.0 million.
- Upon the execution of the Contribution Agreement, we and Shionogi each contributed such party’s share of the Joint Ownership IP into SASS. We accounted for the contribution of our share of the Joint Ownership IP to SASS under ASC 606 as described within Note 10 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report. In accordance with ASC 606, we reclassified $14.7 million of the initial deposit liability recorded as of

December 31, 2024 to deferred revenue using the relative fair value method relating to the Atomoxetine Licensed IP as described in Note 10 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report.

- The Joint Ownership IP contributed to SASS resulted in an increase to the equity method investment of $62.2 million, of which $25.0 million was allocated to the Desitin IP and $37.2 million was allocated to the Atomoxetine Licensed IP. Of the amounts allocated to the Atomoxetine Licensed IP, $14.7 million was reclassified from the initial deposit liability and $22.5 million from the cash received upon execution of the Joint Ownership Agreement.
- SASS accounted for the contribution of the Joint Ownership IP under ASC 730, recording expense equal to the fair value of the contributions as the contributions represented in-process research and development ("IPR&D") with no alternative future use. We recorded our 50% share of the losses from the IPR&D as a reduction of the carrying value of our equity method investment in SASS of $62.2 million.

In April 2026, we completed the SASS Disposition pursuant to the MIPA. We have recorded our equity method investment in SASS as assets held for sale within our condensed consolidated balance sheets as of December 31, 2025 and the impact of the SASS Disposition is reflected in our condensed consolidated statement of operations as discussed in Note 15 to our unaudited condensed consolidated financial statements for the nine months ended September 30, 2026.

Results of Operations

Comparison of three months ended September 30, 2026 and 2025

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Revenue - related party	$ 2,480	$ 8,802	$ (6,322)	(72)%
Operating expenses				
Research and development	11,812	9,754	2,058	21%
General and administrative	22,628	6,045	16,583	274%
Cost of services - related party	245	1,987	(1,742)	(88)%
Total operating expenses	34,685	17,786	16,899	95%
Income (loss) from operations	(32,205)	(8,984)	(23,221)	258%
Interest income	1,814	263	1,551	590%
Change in fair value of long-term debt	1,208	—	1,208	100%
Change in fair value of revenue interest liability	(260)	—	(260)	(100)%
Other expense	(81)	—	(81)	(100)%
Net income (loss) from continuing operations before income taxes	(29,524)	(8,721)	(20,803)	239%
Income tax expense	—	—	—	—
Net income (loss) from continuing operations	(29,524)	(8,721)	(20,803)	239%
Loss from discontinued operations	—	(2,189)	2,189	(100)%
Net income (loss)	$ (29,524)	$ (10,910)	$ (18,614)	171%

Revenue - Related Party

During the three months ended September 30, 2026, we recognized revenue from related party of $2.5 million compared to $8.8 million for the comparable prior year period. The decrease of $6.3 million, or 72%, is primarily driven by a decrease in research and development services provided to SASS due to the conclusion of the SASS RESTEADY trial.

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Oxnimbi	$ 2,517	$ 4,495	$ (1,978)	(44)%
Connected wearables	219	222	(3)	(1)%
Medical affairs	2,709	618	2,091	338%
Other projects	7	14	(7)	(50)%
Employee-related expenses	5,369	4,053	1,316	32%
Stock-based compensation	991	352	639	182%
Total research and development expenses	$ 11,812	$ 9,754	$ 2,058	21%

Research and development expenses for the three months ended September 30, 2026 were $11.8 million, compared to $9.8 million for the comparable prior year period. The increase of $2.0 million, or 21%, was primarily due to an increase of $2.1 million in medical affairs expense due to increased Key Opinion Leader ("KOL") engagement in 2026, higher employee-related expenses of $1.3 million and stock-based compensation of $0.6 million, This increase was partially offset by $2.0 million lower clinical trial expense related to Oxnimbi as we focus on commercial launch.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
General and administrative	$ 12,191	$ 4,059	$ 8,132	200%
Commercial marketing	5,155	1,112	4,043	364%
Stock-based compensation	5,282	874	4,408	504%
Total general and administrative expenses	$ 22,628	$ 6,045	$ 16,583	274%

General and administrative expenses include items related to personnel, including bonus and benefit related expenses, legal services, rent and utilities, general consulting services and other office-related expenses. General and administrative expenses for the three months ended September 30, 2026 were $12.2 million, compared to $4.1 million for the comparable prior year period, representing an increase of $8.1 million, or 200%, primarily due to professional services expenses incurred related to business consulting and contract negotiations, IT infrastructure, and increased salary and related employee expenses due to increased headcount.

Commercial marketing expense was $5.2 million for the three months ended September 30, 2026, compared to $1.1 million for the comparable prior year period. The increase of $4.0 million, or 364%, was due to an increase in infrastructure to prepare us, the market, and our brand for the expected launch of Oxnimbi, if approved, including in key areas such as education on the unmet needs in OSA, pricing strategy, forecast estimates, market access planning, product positioning and stakeholder messaging.

Stock-based compensation was $5.3 million for the three months ended September 30, 2026, compared to $0.9 million for the comparable prior year period. The increase of $4.4 million, or 504%, is primarily driven by stock-based compensation expense recognized in connection with employee award modifications during the period, as well as increased headcount.

We expect general and administrative expenses will continue to increase as we hire additional personnel to prepare our company for future growth and to operate as a public company.

Cost of Services - Related Party

The following table summarizes our related-party cost of services for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Cost of services - related party	$ 245	$ 1,987	$ (1,742)	(88)%

During the three months ended September 30, 2026, we recognized cost of services of $0.2 million related to SASS, compared to $2.0 million of related-party cost of services for the comparable prior year period. This decrease of $1.7 million, or 88%, is due to decreased services provided to SASS as the SASS RESTEADY trial has concluded.

Other Income

The following table summarizes our other income for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Interest income	$ 1,814	$ 263	$ 1,551	590%
Change in fair value of long-term debt	1,208	—	1,208	100%
Change in fair value of revenue interest liability	(260)	—	(260)	(100)%
Other expense	(81)	—	(81)	(100)%
Total other income	$ 2,681	$ 263	$ 2,418	919%

Other income for the three months ended September 30, 2026 was $2.7 million, compared to $0.3 million for the comparable prior year period. The increase of $2.4 million was due to a $1.6 million increase in interest income due to increase in cash, and $1.2 million increase in fair value of our long-term debt, offset by $0.3 million change in fair value of revenue interest liability.

Loss from Discontinued Operations

Loss from discontinued operations represents our share of the losses recorded by SASS. Our loss from discontinued operations for the three months ended September 30, 2026 was zero, compared to $2.2 million for the comparable prior year period. This decrease is due to the completion of the SASS Disposition pursuant to the MIPA on April 6, 2026.

Comparison of nine months ended September 30, 2026 and 2025

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Revenue - related party	$ 99,374	$ 29,043	$ 70,331	242%
Operating expenses				
Research and development	29,816	49,179	(19,363)	(39)%
General and administrative	41,808	16,868	24,940	148%
Cost of services - related party	3,615	5,028	(1,413)	(28)%
Total operating expenses	75,239	71,075	4,164	6%
Income (loss) from operations	24,135	(42,032)	66,167	(157)%
Interest income	3,002	1,003	1,999	199%
Gain on reversal of deposit liability	57,120	—	57,120	100%
Change in fair value of long-term debt	(451)	—	(451)	(100)%
Change in fair value of revenue interest liability	(720)	—	(720)	(100)%
Change in fair value of convertible notes	1,315	—	1,315	100%
Other expense	(2,819)	—	(2,819)	(100)%
Net income (loss) from continuing operations before income taxes	81,582	(41,029)	122,611	(299)%
Income tax expense	—	—	—	0%
Net income (loss) from continuing operations	81,582	(41,029)	122,611	(299)%
Gain on sale of equity method investment	85,380	—	85,380	100%
Loss from discontinued operations	(2,832)	(68,001)	65,169	(96)%
Net income (loss) from discontinued operations	82,548	(68,001)	150,549	(221)%
Net income (loss)	$ 164,130	$ (109,030)	$ 273,160	(251)%

Revenue - Related Party

During the nine months ended September 30, 2026, we recognized revenue for research and development services for SASS of $99.4 million compared to $29.0 million for the comparable prior year period. The increase of $70.3 million was primarily driven by the change in estimated costs to be incurred in providing services pursuant to the SASS MSA, as amended, as a result of entering into the MIPA. As a result of the change in estimate, the measure of progress toward completion of the one performance obligation was adjusted in accordance with ASC 606 under the cumulative catch-up method. The change in accounting estimate resulted in an

increase in revenue of $81.3 million. The increase was partially offset by a reduction in research and development services provided to SASS due to the MIPA and the conclusion of the SASS RESTEADY trial.

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Oxnimbi	$ 8,037	$ 29,981	$ (21,944)	(73)%
Connected wearables	783	812	(29)	(4)%
Medical affairs	5,494	3,666	1,828	50%
Other projects	29	821	(792)	(96)%
Employee-related expenses	13,740	12,874	866	7%
Stock-based compensation	1,733	1,025	708	69%
Total research and development expenses	$ 29,816	$ 49,179	$ (19,363)	(39)%

Research and development expenses for the nine months ended September 30, 2026 were $29.8 million, compared to $49.2 million for the comparable prior year period. The decrease of $19.4 million, or 39%, was primarily due to approximately $22.0 million of lower expenses related to Oxnimbi as the LunAIRo and SynAIRgy trials were completed in 2025 and $0.8 million of decreased preclinical activity as we continued to prioritize commercialization efforts for Oxnimbi, if approved. These decreases were offset by approximately $0.8 million increase in personnel costs and $0.7 million increase in stock-based compensation due to increased headcount, and $1.8 million increase in medical affairs due to increased KOL engagement in 2026, including medical communication and medical congresses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
General and administrative	$ 23,879	$ 12,299	$ 11,580	94%
Commercial marketing	11,269	2,700	8,569	317%
Stock-based compensation	6,660	1,869	4,791	256%
Total general and administrative expenses	$ 41,808	$ 16,868	$ 24,940	148%

General and administrative expenses include items related to personnel, including bonus and benefit related expenses, legal services, rent and utilities, general consulting services and other office-related expenses. General and administrative expenses for the nine months ended September 30, 2026 were $23.9 million, compared to $12.3 million for the comparable prior year period, representing an increase of $11.6 million, or 94% primarily due to professional services expenses incurred related to business consulting and contract negotiations, IT infrastructure, and increased salary and related employee expenses due to increased headcount.

Commercial marketing expense was $11.3 million for the nine months ended September 30, 2026, compared to $2.7 million for the comparable prior year period. The increase of $8.6 million, or 317%, was primarily due to an increase in infrastructure to prepare us, the market and our brand for the expected launch of Oxnimbi, if approved, including in key areas such as education on the unmet needs in OSA, pricing strategy, forecast estimates, market access planning, product positioning and stakeholder messaging.

Stock-based compensation was $6.7 million for the nine months ended September 30, 2026, compared to $1.9 million for the comparable prior year period. The increase of $4.8 million, or 256%, was primarily driven by stock-based compensation expense recognized in connection with employee award modifications during the period, as well as increased headcount.

We expect general and administrative expenses will continue to increase as we hire additional personnel to prepare our company for future growth and to operate as a public company.

Cost of Services - Related Party

The following table summarizes our related-party cost of services for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Cost of services - related party	$ 3,615	$ 5,028	$ (1,413)	(28)%

During the nine months ended September 30, 2026, we recognized cost of services of $3.6 million, compared to $5.0 million for the comparable prior year period. The decrease of $1.4 million, or 28%, was primarily driven by decreased research and development activities related to sulthiame before the MIPA and the conclusion of the SASS RESTEADY trial.

Other Income

The following table summarizes our other income for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Interest income	$ 3,002	$ 1,003	$ 1,999	199%
Gain on reversal of deposit liability	57,120	—	57,120	100%
Change in fair value of long-term debt	(451)	—	(451)	(100)%
Change in fair value of revenue interest liability	(720)	—	(720)	(100)%
Change in fair value of convertible notes	1,315	—	1,315	100%
Other expense	(2,819)	—	(2,819)	(100)%
Total other income	$ 57,447	$ 1,003	$ 56,444	5,628%

Other income for the nine months ended September 30, 2026 was $57.4 million, compared to $1.0 million for the comparable prior year period. The increase of $56.4 million, or 5,628% was primarily due to a gain on reversal of deposit liability of $57.1 million following the termination of the ROFN, and $1.3 million gain resulting from a change in the fair value of our convertible notes issued in September 2025 (the "Convertible Notes"), and a $2.0 million increase in interest income. These increases were partially offset by $1.2 million of expenses driven by the changes in fair value of our long-term debt and revenue interest liability, as well as an increase in other expenses of $2.8 million primarily related to $2.9 million of long-term debt issuance costs, partially offset by $0.1 million change in fair value of our contingent asset recorded as part of the consideration received pursuant to the SASS Disposition.

Income (Loss) from Discontinued Operations

Our income from discontinued operations for the nine months ended September 30, 2026 was $82.5 million, compared to a loss of $68.0 million for the comparable prior year period. This increase of $150.5 million, or 221%, is primarily driven by a gain on sale of equity method investment of $85.4 million upon completion of the SASS Disposition pursuant to the MIPA in April 2026, and a $65.2 million decrease in our share of losses recorded by SASS. The reduction in SASS-related losses was primarily driven by the absence of the $62.2 million charge incurred in April 2025 related to SASS expensing of IPR&D related to the contribution of the Desitin IP and the Atomoxetine Licensed IP. Additionally, as a result of the SASS Disposition pursuant to the MIPA in April 2026, we recognized fewer months of SASS-related losses in the nine months ended September 30, 2026.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred operating losses and negative cash flows from our operations. We have not recognized any sales revenue, other than revenue generated from services provided to SASS, and have not commercialized any products.

From inception, we have funded our operations primarily through equity financings and debt. As of September 30, 2026, we have raised aggregate gross proceeds of approximately $759.9 million, consisting of $389.1 million from the sale of shares of our preferred stock, common stock, Convertible Notes and entry into the ROFN Agreement, $49.0 million from our Credit Agreement, and $100.0 million from SASS, $1.0 million from a license option agreement with Morningside Venture Investments Limited and gross proceeds of $220.8 million from the sale of shares of common stock in our IPO in August 2026, which resulted in net proceeds of $198.9 million after deducting underwriter discounts and commissions and other offering expenses. As of September 30, 2026, we had cash and cash equivalents of $351.8 million.

Credit Agreement

In April 2026, we entered into the Credit Agreement with the Agent and the Lenders. The Credit Agreement provides for up to $150.0 million of term loans (the "Term Loans"), available to us in multiple tranches. Additionally, in connection with the Credit Agreement, we issued warrants to purchase 100,163 shares of our common stock (the “Warrants”) to the Lenders. In April 2026, the Lenders advanced $50.0 million of Term Loans (the "Tranche A Term Loan") to us. Additionally, we will be entitled to receive an advance of $50.0 million (the "Tranche B Term Loan") upon our receipt of regulatory authorization from the FDA for Oxnimbi with a labeled indication for the treatment of OSA in any adult population (the "Tranche B Milestone Event") and an additional advance of $50.0 million (the “Tranche C Term Loan”) if, on or prior to June 30, 2028, the trailing twelve-month net sales of the products covered by the Amended and Restated Exclusive Patent License Agreement with BWH dated December 29, 2020 (as further amended

on July 27, 2023, the “BWH License”) equals or exceeds $175.0 million (the "Tranche C Milestone Event"), in each case subject to certain other conditions as set forth in the Credit Agreement. The Tranche B Term Loan is available through June 30, 2027, subject to the satisfaction of the conditions specified in the Credit Agreement. The Tranche C Term Loan is available through September 30, 2028, subject to the satisfaction of the conditions specified in the Credit Agreement. The Term Loans mature on April 2, 2031. Pursuant to a Security Agreement we entered into in April 2026 with the Agent and the Lenders (the “Security Agreement”), our obligations under the Credit Agreement are secured by a lien on substantially all of our assets, including our intellectual property (the "Collateral").

Outstanding Term Loans accrue interest at an annual rate equal to the Three-Month Term SOFR (as defined in the Credit Agreement) plus 5.75%, subject to potential reductions of up to one percent upon completion of certain events specified in the Credit Agreement (the “Credit Agreement Interest Rate”). In addition to interest on the outstanding Term Loans, we agreed to pay an additional revenue interest on each quarterly payment date, beginning May 15, 2026, calculated as a percentage of our net revenues equal to a low single digit percentage on the portion of annual net revenues up to $200.0 million and an amount below one percent on the portion of annual net revenues between $200.0 million and $500.0 million, in each case until the earlier of the ten-year anniversary of the first commercial sale of Oxnimbi or earlier extinguishment pursuant to the terms of the Credit Agreement (collectively, the “Revenue Interest Payments”).

We are permitted to voluntarily prepay the Term Loans from time to time, in whole and in part and are required to prepay the Term Loans upon receipt of proceeds from certain asset sales, extraordinary receipts and debt incurrences, subject, in each case, to certain exceptions set forth in the Credit Agreement. All prepayments (other than prepayments upon a change of control as such term is defined in the Credit Agreement) are subject to a prepayment premium equal to a make-whole amount (reflective of all interest that would have accrued on such prepaid amount from April 2, 2026 to April 2, 2028) plus 5.0% if made on or prior to April 2, 2028, 4.00% if made after April 2, 2028 and on or prior to April 2, 2029, 2.50% if made after April 2, 2029 and on or prior to April 30, 2029, and 0.00% thereafter. Mandatory prepayments are required from net cash proceeds from dispositions, involuntary dispositions, extraordinary receipts and debt issuances. In addition, upon any prepayment or repayment (other than in connection with a change of control), we are required to pay a final payment premium equal to 4.0% of the portion of the applicable Term Loan amount being repaid.

The Credit Agreement contains various affirmative and negative covenants, which are subject to customary exceptions, that limit our ability to engage in specified types of transactions without the prior written consent of the Lenders. In addition, we are required to deposit into controlled accounts all cash or other payments received with respect to any and all of our accounts receivable or any other contract or right and interest and, at all times, to maintain a minimum aggregate balance of $20.0 million in cash in one or more such controlled accounts. These accounts are required to be maintained as cash collateral accounts securing our obligations under the Credit Agreement. Until our obligations under the Credit Agreement have been discharged, our ability to use the cash amounts held in these controlled accounts in the operation of our business will be limited.

In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Credit Agreement, subject to customary grace periods, the Lenders may elect to declare all amounts outstanding to be immediately due and payable, terminate all commitments to extend further credit and exercise other remedies available to secured lenders in accordance with law. If we are unable to repay the amounts due under the Credit Agreement or otherwise perform our obligations under the Credit Agreement, the Lenders could proceed against the Collateral granted to them to secure our obligations under the Credit Agreement, as further specified under the Security Agreement, potentially requiring us to renegotiate our Credit Agreement on terms materially less favorable to us or to immediately cease operations, which would have a material adverse effect on our business, financial condition and results of operations.

Notes

In September 2025, we issued the Convertible Notes in the aggregate principal amount of $35.0 million, as amended by the First Amendment to the Convertible Notes, entered in March 2026 (the "Note Amendment"). The Convertible Notes bore an interest rate of 8% annually through March 31, 2026. Thereafter, the Convertible Notes bear an interest rate of 15% annually until such time as the Convertible Notes are repaid or converted. The outstanding amount of the Convertible Notes was automatically converted into an aggregate of 2,646,838 shares of our common stock immediately prior to the closing of our IPO, at a conversion price of $14.40 per share, which is a 10% discount to the purchase price per share at which shares of our common stock were sold to the public in our IPO (before underwriting discounts and commissions).

SASS MIPA

In April 2026, we completed the SASS Disposition pursuant to the MIPA. As partial consideration under the MIPA, we received the Closing Payment of $100.0 million. In addition, we are eligible to receive (a) a one-time Milestone Payment of $50.0 million, payable upon the earlier of (i) the MIPA Clinical Development Milestone or (ii) the MIPA Regulatory Milestone and (b) the MIPA Earnout Payments (as defined below in this section).

We are also entitled to receive earnout payments equal to a mid to low single digit percentage of net sales of products that incorporate a JV Compound and are further developed or commercialized by the Earnout Parties (each, an "Earnout Product") with the percentage of net sales varying based on the JV Compound used in the applicable Earnout Product (the "MIPA Earnout Payments" and, together with the Closing Payment and the Milestone Payment, the "Purchase Price"). The calculation of net sales of any Earnout Product that is a combination of one or more JV Compounds and one or more proprietary compounds is subject to an apportionment process as between the JV Compound(s) and the proprietary compound(s) used in such Earnout Product.

Future Funding Requirements

As of September 30, 2026, we had cash and cash equivalents of $351.8 million. We expect to incur significant expenses and operating losses for the foreseeable future as we seek regulatory approval and pursue commercialization of Oxnimbi and advance any future product candidates through nonclinical and clinical development. We expect that our general and administrative costs will increase substantially in connection with our planned commercialization activities. In addition, we expect to incur additional costs associated with operating as a public company.

In April 2026, we received the Closing Payment of $100.0 million pursuant to the MIPA and an advance from the Lenders of $50.0 million under the Credit Agreement. Pursuant to the MIPA, we may receive the Milestone Payment, subject to the achievement of (i) the MIPA Clinical Development Milestone or (ii) the MIPA Regulatory Milestone, and the MIPA Earnout Payments, based on net sales of the applicable Earnout Product. Pursuant to the Credit Agreement, we will be entitled to receive (i) the Tranche B Term Loan, equal to $50.0 million, upon the achievement of the Tranche B Milestone Event and (ii) the Tranche C Term Loan, equal to $50.0 million, upon the achievement of the Tranche C Milestone Event, in each case subject to certain other conditions as set forth in the Credit Agreement. Since we will only be eligible to receive these amounts upon the occurrence of the events described above, there is no guarantee we will receive any of these additional funds. We otherwise do not have any committed external source of funds. Until we can generate a sufficient amount of revenue from the commercialization of Oxnimbi or any future product candidates, if ever, or from collaboration agreements with third parties, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. The Credit Agreement subjects us to and any future debt financings may subject us to additional covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and fluctuations in interest rates, resulting from factors that include but are not limited to, inflation, global and regional conflicts and other factors, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary additional debt or equity financings more difficult, more costly and more dilutive. If we raise additional funds through future collaborations, licenses, or other similar arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, product candidates, research programs intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us or may reduce the value of our common stock. For example, under the terms of the MIPA, we are subject to a five year worldwide non-competition obligation in relation to the exploitation of any product containing a JV Compound for the treatment, prevention or mitigation of sleep disorders.

There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market Oxnimbi or any future product candidates ourselves or on less favorable terms than we would otherwise choose.

We expect our expenses to increase substantially if we receive regulatory approval for Oxnimbi as we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. Our future capital requirements will depend on a number of factors, including:

- the costs, timing and outcome of regulatory review of any of Oxnimbi or any future product candidates;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Oxnimbi or any future product candidates for which we receive marketing approval;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved product, should Oxnimbi or any future product candidates receive marketing approval;
- the costs and timing of manufacturing of Oxnimbi or any future product candidate, including commercial manufacture at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the amount of revenue, if any, received from commercial sales of Oxnimbi or any future product candidates, should such product candidates receive marketing approval;
- the rate of progress in the development of Oxnimbi and any future product candidates;
- the initiation, type, scope, rate of progress and expenses of our ongoing research activities, as well as any preclinical studies and clinical trials and other research and development activities for Oxnimbi or any future product candidates;
- the initiation, type, number and scope of clinical programs we decide to pursue;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, CMOs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- our ability to establish and maintain collaborations, licenses and other similar arrangements on favorable terms;
- delays, challenges or other issues associated with any of the above, including the failure of clinical trials meeting endpoints, the generation of unanticipated nonclinical study results or clinical trial data subject to differing interpretations, or the occurrence of potential safety issues or other development or regulatory challenges;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time, including the BWH License;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage or adequate reimbursement from third-party payors;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the costs of building out internal accounting, legal, compliance and other operational and administrative functions and other costs associated with operating as a public company; and
- the other risks and uncertainties described in "Risk Factors," "Special Note Regarding Forward-Looking Statements" and elsewhere in this Quarterly Report and in the registration statement on Form S-1, as amended (File No. 333-297377) (the "Registration Statement") filed with the SEC in connection with our IPO.

A change in the outcome of any of these or other variables could significantly change our costs and timing associated with the development of Oxnimbi or any future product candidates. Furthermore, our operating plans may change in the future and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (59,107)	$ (63,097)
Net cash provided by investing activities	99,664	—
Net cash provided by financing activities	269,879	51,364
Net increase/(decrease) in cash, cash equivalents and restricted cash	$ 310,436	$ (11,733)

Cash Flows from Operating Activities

We have experienced negative operating cash outflows as we continue clinical development of Oxnimbi. Our net cash used in operating activities primarily results from our net income (loss) adjusted for non-cash expenses and changes in working capital components. Our primary uses of cash from operating activities are amounts due to CROs to conduct our clinical programs and employee-related expenditures for research and development and general and administrative activities, and infrastructure costs to prepare us, the market and our brand for the expected launch of Oxnimbi, if approved, . Our cash flows from operating activities will continue to be affected by spending to advance and support our clinical development and other operating and general administrative activities.

Net cash used in operating activities was $59.1 million for the nine months ended September 30, 2026, primarily consisting of the net changes in operating assets and liabilities of $152.0 million, primarily driven by decreases in deferred revenue of $95.8 million and deposit liabilities of $57.1 million, as well as a gain on sale of equity method investment of $85.4 million. These uses of cash were partially offset by our net income of $164.1 million and other non-cash charges of $14.1 million, primarily related to changes in the fair value of financial instruments, stock-based compensation, debt issuance costs, and loss from discontinued operations.

Net cash used in operating activities was $63.1 million for the nine months ended September 30, 2025, primarily consisting of our net loss of $109 million related to clinical development activities and net changes in operating assets and liabilities of $25.0 million. These uses of cash were partially offset by non-cash charges of $68.0 million related to loss from discontinued operations, and $2.9 million related to stock-based compensation.

Cash Flows from Investing Activities

Net cash provided by investing activities was $99.7 million for the nine months ended September 30, 2026, primarily consisting of net proceeds from the sale of equity method investment. We did not have any cash flows from investing activities for the nine months ended September 30, 2025.

Cash Flows from Financing Activities

Net cash provided by financing activities was $269.9 million for the nine months ended September 30, 2026, primarily driven by $198.9 million of net proceeds received from our IPO in August 2026, $45.3 million of net proceeds received from our Credit Agreement, $24.8 million of net proceeds received from the issuance of our Series D-1 preferred stock, $0.8 million net proceeds received from issuance of Warrants and $0.1 million proceeds received from exercise of stock options.

Net cash provided by financing activities was $51.4 million for the nine months ended September 30, 2025, driven by $16.3 million of net proceeds from the issuance of our Series D preferred stock, $35.0 million of proceeds from the issuance of the Convertible Notes and $0.1 million proceeds received from exercise of stock options.

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Contractual Obligations and Commitments

As of September 30, 2026, there have been no material changes to our contractual obligations or commitments as compared to those described in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Registration Statement.

Critical Accounting Policies and Significant Judgments and Estimates

This management’s discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. On an ongoing

basis, we evaluate our estimates and assumptions. Our estimates are based on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Registration Statement for further information on our critical accounting estimates and policies.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2—"Summary of Significant Accounting Policies" to our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the time that we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means, among other things, the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies for so long as either (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act 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.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level as a result of a material weakness in our internal control over financial reporting discussed below.

In connection with the audit of our consolidated financial statements as of and for the years ended December 31, 2025 and 2024, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a

combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness relates to an ineffective control environment, including a lack of formal documented risk assessment and monitoring controls, insufficient information technology controls, including access and change management controls over financial reporting, and a lack of sufficient levels of accounting personnel to maintain proper control activities over classification, valuation and disclosure over non-routine or complex transactions.

Remediation Plans

We started our remediation efforts during the year ended December 31, 2024 and efforts have continued into 2026. In 2025, we implemented a new enterprise resource planning system, and designed a risk assessment process. Also, in 2025 and into 2026, we've continued to hire additional resources to support accounting and finance. In an effort to continue to remediate this material weakness, we intend to design and implement processes and internal controls over our information and technology, finalize and document our risk assessment, and further develop and document our accounting policies and financial reporting procedures, including documenting our senior management and audit committee oversight.

We are focused on designing and implementing effective internal control measures to improve our evaluation of disclosure controls and procedures, including internal control over our information technology and related financial reporting, and remediating the material weakness. See the section titled "Risk Factors—We have previously identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate a material weakness or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results and may adversely affect stockholder confidence and business operations."

Changes in Internal Control over Financial Reporting

There have been 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, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. All of the risks and uncertainties described below should be considered and read carefully, as well as the other information in this Quarterly Report, including our financial statements and the related notes appearing elsewhere in this Quarterly Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our common stock. The risks described below are not the only risks facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could cause our business, prospects, operating results and financial condition to suffer materially.

This Quarterly Report also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Operating History, Financial Condition and Need for Additional Capital

We are a late-stage clinical pharmaceutical company and have incurred significant operating losses since our inception and we expect to incur significant operating losses for the foreseeable future. We may never become profitable and, if profitability is ever achieved, we may not be able to sustain it.

We are a late-stage clinical pharmaceutical company with a limited operating history upon which stockholders can evaluate our business and prospects, and we have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future as we seek U.S. Food and Drug Administration (the "FDA") approval and begin commercial launch for Oxnimbi, if approved. As an organization, we have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture products at commercial scale, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, 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 history of successfully developing and commercializing sleep apnea and other sleep breathing disease products.

We have no products approved for commercial sale and have not generated any commercial revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. Our net loss was $128.2 million for the year ended December 31, 2025 and net income of $164.1 million and net loss of $109 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had cash and cash equivalents of $351.8 million. As of September 30, 2026, we had an accumulated deficit of $233.2 million. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance and, if Oxnimbi or any future product candidate is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the incurrence of further significant operating losses for the foreseeable future.

We may not be profitable even if we succeed in commercializing Oxnimbi or any future product candidates. We anticipate that our expenses will increase substantially as we:

- seek FDA approval for Oxnimbi and prepare to launch and commercialize Oxnimbi in the United States, if approved;
- experience an increase in headcount as we expand our organization for our planned commercialization efforts;
- scale up manufacturing to accommodate demand for Oxnimbi, if approved, for commercialization;
- undertake pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- initiate additional clinical and other studies for Oxnimbi or any future product candidates;
- continue nonclinical and discovery efforts for our current and future programs;
- implement effective and robust promotional messaging and compliance controls for promotional labeling and advertising materials and activities for Oxnimbi, if approved, for commercialization;
- establish and expand manufacturing capabilities and supply chain capacity for Oxnimbi or any future product candidates;

- hire additional research and development, clinical, commercial and operational personnel;
- experience any delays, challenges or other issues associated with any of the above, including the failure of clinical trials meeting endpoints, the generation of unanticipated nonclinical study results or clinical trial data subject to differing interpretations or the occurrence of potential safety issues or other development or regulatory challenges;
- seek to identify, acquire and develop additional research programs, product candidates, intellectual property or technologies to build a pipeline, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with an exchange listing and the U.S. Securities and Exchange Commission ("SEC") requirements, director and officer insurance premiums, and stockholder relations costs;
- establish and maintain collaborations; and
- make milestone, royalty or other payments due under our Amended and Restated Exclusive Patent License Agreement with BWH dated December 29, 2020 (as further amended on July 27, 2023, the "BWH License"), the Membership Interest and Asset Purchase Agreement with Shionogi & Co., Ltd. ("Shionogi") and Shionogi-Apnimed Sleep Science, LLC ("SASS"), dated as of March 23, 2026, as amended on April 6, 2026 (the "MIPA") and any future in-license, assignment, purchase or collaboration agreements.

Pharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable and, therefore, any investment in us is highly speculative. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, Oxnimbi or any future product candidates we may develop. Successful commercialization will require achievement of many key milestones, which vary by jurisdiction and may include demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for Oxnimbi or any future product candidates, manufacturing, marketing and selling those products for which we, or any of our current or future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the extent of any further losses, the timing and amount of revenues or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are large enough for us to achieve profitability and 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.

Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We may encounter risks and difficulties, known and unknown, that are frequently experienced by late stage companies in rapidly evolving fields. As we advance Oxnimbi or any future product candidates, we must transition from a company with a clinical development focus to a company capable of supporting commercial activities, if we receive FDA approval. We may not be successful in such transitions. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, you should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

If we continue to suffer losses and if we do not achieve or sustain profitability, our stockholders may not receive any return on their investment and may lose their entire investment. Accordingly, before making an investment in us, a stockholder should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development and product approval, especially late-stage clinical pharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

In April 2026, we entered into a term loan facility (the "Credit Agreement") with HCRx Investments HoldCo, L.P., HCR Stafford Fund II, L.P. and HCR Potomac Fund II, L.P (the "Lenders") and HCR OSA SPV, LLC, as administrative agent and

collateral agent (the "Agent"). The Credit Agreement provides for up to $150.0 million of term loans (the "Term Loans"), available to us in multiple tranches. In April 2026, the Lenders advanced $50.0 million of term loans (the "Tranche A Term Loan") to us. Additionally, we will be entitled to receive an advance of $50.0 million (the "Tranche B Term Loan") upon our receipt of regulatory authorization from the FDA for Oxnimbi with a labeled indication for the treatment of obstructive sleep apnea ("OSA") in any adult population (the "Tranche B Milestone Event") and an additional advance of $50.0 million (the "Tranche C Term Loan") if, on or prior to June 30, 2028, the trailing twelve-month net sales of the products covered by the BWH License equals or exceeds $175.0 million (the "Tranche C Milestone Event"). Since the availability of the Tranche B Term Loan and the Tranche C Term Loan are subject to the achievement of certain regulatory and commercial milestones and other conditions set forth in the Credit Agreement, there can be no guarantee that we will be able to access any future tranches.

Outstanding Term Loans will mature on April 2, 2031. Outstanding Term Loans accrue interest at an annual rate equal to Three-Month Term SOFR (as defined in the Credit Agreement) plus 5.75%, subject to potential reductions of up to one percent upon completion of certain events specified in the Credit Agreement (the "Credit Agreement Interest Rate"). In addition to interest on the outstanding Term Loans, we agreed to pay an additional revenue interest on each quarterly payment date, beginning May 15, 2026, calculated as a percentage of our net revenues equal to a low single digit percentage on the portion of annual net revenues up to $200.0 million and an amount below one percent on the portion of annual net revenues between $200.0 million and $500.0 million, in each case until the earlier of the ten-year anniversary of the first commercial sale of Oxnimbi or earlier extinguishment pursuant to the terms of the Credit Agreement (collectively, the "Revenue Interest Payments"). Our future operating performance is subject to market conditions and business factors that are beyond our control. Additionally, a portion of our cash flow from operations will be needed to make payments pursuant to the Credit Agreement and will not be available to fund future operations. If our cash inflows and capital resources are insufficient to allow us to make required payments under the Credit Agreement, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. Additionally, pursuant to a Security Agreement entered into in April 2026 with the Agent and the Lenders (the "Security Agreement"), our obligations under the Credit Agreement are secured by a lien on substantially all of our assets, including our intellectual property (the ″Collateral"). For more information, see the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Credit Agreement” included elsewhere in this Quarterly Report.

The Credit Agreement contains customary covenants that could prevent us from taking certain actions without the consent of the Lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders.

The Credit Agreement also contains customary events of default, including the failure to make payments when due or comply with other covenants therein. We intend to satisfy our current and future debt service obligations with our then-existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing to pay the amounts due under Credit Agreement or any other debt instruments. Upon the occurrence and continuance of an event of default, the Lenders may accelerate all of our repayment obligations and take control of the Collateral, potentially requiring us to renegotiate our Credit Agreement on terms materially less favorable to us or to immediately cease operations. Any declaration by the Lenders of an event of default would significantly harm our business and prospects and could cause the price of our common stock to decline. If we obtain any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We will require substantial additional funding in order to finance our operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we seek regulatory and marketing approval for Oxnimbi and conduct pre-clinical studies and clinical trials for any future product candidates. Even if Oxnimbi or any future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. We cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of Oxnimbi or any other future product candidates. We have funded our operations principally through private financings and recently entered into the Credit Agreement, as described elsewhere in this Quarterly Report. We may also need to raise additional funds sooner if we choose to pursue additional indications or geographies for Oxnimbi or any future product candidates or otherwise expand more rapidly than we presently anticipate. To the extent that we raise additional capital through the sale of equity or convertible securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. In addition, additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we incur additional debt, including under the Credit Agreement, such creditors would have rights senior to common stockholders to make claims on our assets. If we raise additional funds through collaborations, strategic alliances or marketing,

distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or products or grant licenses on terms that may not be favorable to us.

As of September 30, 2026, we had $351.8 million of cash and cash equivalents. Based upon our current operating plan, we believe that our cash and cash equivalents as of September 30, 2026, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. However, our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the timing and costs involved in obtaining FDA approval for Oxnimbi or any future product candidate is uncertain. Further, our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our cash and cash equivalents as of September 30, 2026, may not be sufficient to successfully launch and commercialize Oxnimbi, if approved. We may also raise additional financing on an opportunistic basis or incur additional debt in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert the attention of our management from our day-to-day activities, which may adversely affect our ability to develop Oxnimbi or any future product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the timing of, and the costs involved in, pursuing regulatory review and marketing approval for Oxnimbi or any future product candidates;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of Oxnimbi or any future product candidates;
- requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for Oxnimbi or any future product candidates and our anticipated timing for seeking approval in such jurisdictions;
- if approved, the costs of commercialization activities for Oxnimbi, or any future product candidate that receives regulatory approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- if approved, our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors for Oxnimbi and adequate market acceptance, market share and revenue for any approved product;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage or adequate reimbursement from third-party payors;
- the number and size of clinical trials required for regulatory approval of Oxnimbi or any future product candidates;
- the number of future product candidates that we may pursue and their development requirements;
- the scope, timing, progress, costs and results of discovery, nonclinical development and clinical trials for Oxnimbi or any future product candidates, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the scope, timing, progress, costs and results of any post-marketing study or pediatric study requirements for Oxnimbi or any future product candidates that receive approval;
- our ability to scale manufacturing capabilities and to identify alternative manufacturing sources, if needed;
- our ability to address any potential supply chain interruptions or delays;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish and maintain collaborations, licenses, and other similar arrangements on favorable terms;
- the achievement of milestones or occurrence of other developments that trigger payments under any license, purchase or collaboration agreements we might be party to at such time, including the BWH License and the MIPA;

- our headcount growth and associated costs as we expand our business operations and research and development activities and prepare to establish a commercial infrastructure;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the effect of macroeconomic trends including inflationary pressures and interest rates.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for Oxnimbi or any future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations.

Risks Related to the Development and Regulatory Approval of AD109 (Proposed Proprietary Name Oxnimbi) and Any Future Product Candidates

Our business depends on the success of our sole clinical product candidate, Oxnimbi, which has completed Phase 3 clinical trials. If we are unable to obtain regulatory approval for, or successfully commercialize Oxnimbi, or are significantly delayed in doing so, our business will be materially harmed.

Our business is primarily dependent on our sole clinical product candidate, Oxnimbi, for the treatment of OSA. Oxnimbi has completed two registrational Phase 3 randomized, double-blind, placebo-controlled, parallel-arm trials in adults with mild to severe OSA. Regulatory approval and successful launch and commercialization of Oxnimbi for OSA is critical to the future success of our business. Based on the results of our Phase 3 clinical trials (LunAIRo and SynAIRgy), we submitted a New Drug Application ("NDA") to the FDA in April 2026, which was accepted for review by the FDA in July 2026. Our ability to generate revenues from product sales will depend on us obtaining marketing approval for and commercializing Oxnimbi, and we cannot accurately predict when or if Oxnimbi will be determined by the FDA to be effective in humans for the proposed indication or whether it will receive marketing approval. The FDA will conduct an in-depth review of our NDA following acceptance for filing across the nonclinical, clinical and quality chemistry, manufacturing, and controls ("CMC") areas. In its acceptance letter and in any later communications during its review, the FDA has raised and may continue to raise questions or concerns regarding the adequacy of our NDA to support approval and has requested and may further request additional information, data or analyses to augment its review of the nonclinical, clinical or CMC areas of our application, which could require that we submit amendments to our NDA. The FDA review process is an iterative process and we expect to work diligently with the FDA to satisfy any requests that arise during the review period. However, we may be unable to adequately address or satisfy the FDA’s requests during the review period, which could lead to delays or extensions of the review period, including if any subsequent information submitted to our application as an amendment is treated as a major amendment, or which could lead the FDA to determine our NDA is unapprovable, triggering a complete response letter.

We have invested, and will continue to invest, a significant portion of our time and financial resources in the development and commercialization of Oxnimbi, if approved. The future regulatory and commercial success of Oxnimbi is subject to a number of risks, including the following:

- the interpretation of our nonclinical and clinical data including, but not limited to the clinical meaningfulness of Oxnimbi for the treatment of mild, moderate and severe OSA, by regulatory authorities to support marketing approvals and the potential need to conduct additional nonclinical studies or clinical trials, including as applicable, any post-marketing requirements, risk evaluation and mitigation strategy ("REMS"), surveillance programs, or pediatric clinical trials;
- the adequacy of our stability data and manufacturing process to support approval and commercial launch;
- the successful launch of commercial sales of Oxnimbi, if approved;
- any product-related adverse events ("AEs") or serious adverse events ("SAEs") experienced by subjects in our clinical trials or post-market, or by individuals using pharmaceuticals with similar characteristics as Oxnimbi, and product labeling restrictions or limitations that may result, including any boxed warnings;
- the satisfaction of applicable regulatory requirements, including our ability to satisfy applicable rules governing fixed dose combination products;

- our ability to obtain and maintain patent and trade secret protection and regulatory exclusivity for Oxnimbi;
- our ability to make and maintain arrangements with third-party manufacturers, or establish manufacturing capabilities, for both clinical and commercial-scale supplies of Oxnimbi including the costs and timing of manufacturing, including as a result of inflation, any supply chain issues or component shortages;
- our ability to establish sales, marketing and distribution capabilities, if Oxnimbi receives marketing approval, whether alone or in collaboration with others, and the timing, receipt and terms of such marketing approval;
- our ability to implement effective and robust promotional compliance and controls and to avoid scrutiny by the FDA's Office of Prescription Drug Promotion ("OPDP") in the United States and comparable authorities outside the United States;
- the acceptance of oral therapies to treat OSA generally and of Oxnimbi in particular, if approved, by patients, the medical community and third-party payors;
- our ability to obtain and maintain favorable pricing and third-party coverage and adequate reimbursement;
- our ability to maintain an acceptable safety profile following any regulatory approval;
- our ability to pursue indication expansion of Oxnimbi;
- our ability to effectively compete with other therapies, including positive airway pressure ("PAP") and neurostimulation technology;
- our ability to promote and distribute our products, if approved, consistent with all applicable healthcare laws; and
- our ability to attract, hire and retain qualified personnel.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. There is no FDA approved pharmacologic therapy to treat an underlying cause of OSA, neuromuscular dysfunction during sleep. As a result, the regulatory approval process for product candidates such as Oxnimbi is uncertain and may be more expensive and take longer than the approval process for product candidates based on better known or more extensively studied therapies or indications. Leadership changes at the FDA in the current administration may compound this uncertainty. In addition, in connection with its review of our top-line Phase 3 data, the FDA expressed concerns about the clinical meaningfulness of certain endpoint results, including the primary endpoint and the limitations of the patient reported outcomes. They indicated that we need to justify that the data demonstrate clinically meaningful change for the treatment of OSA. We submitted information in response to these concerns in our NDA submission and plan to continue to address them and related requests as part of the FDA review process. If we are unable to address these concerns to the FDA's satisfaction, the FDA may determine that the clinical response results from our Phase 3 trials are not clinically meaningful to establish substantial evidence of effectiveness for Oxnimbi in OSA, or that the overall risk-benefit profile of Oxnimbi does not support approval or it may require additional data, analyses or studies to support approval. Furthermore, even if we receive regulatory approval to market Oxnimbi, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the drug. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development program for Oxnimbi, we may be unable to successfully develop or commercialize Oxnimbi, if approved. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize Oxnimbi, or if we experience delays as a result of the above factors or otherwise, we may not be able to generate sufficient revenue to continue our business.

If our clinical trials fail to demonstrate results satisfactory to the FDA or replicate positive results from earlier preclinical studies or clinical trials conducted by us or by third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize Oxnimbi or any future product candidates.

The results observed from preclinical studies or early-stage clinical trials of Oxnimbi or any future product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development or approval of Oxnimbi or any future product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or unexpected or adverse safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse effects.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, European Medicines Agency ("EMA") or comparable foreign regulatory authority approval. There can be no assurance that we will not suffer similar setbacks despite data observed in earlier studies. In addition, the design of a clinical trial can determine whether its results will support approval of Oxnimbi or any future product candidates, and flaws in the design of a clinical trial may not be apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial that will support regulatory approval. Additionally, prescription drug development in the therapeutic field of OSA is relatively novel without extensive prior FDA approvals in the field. As a result, the primary and secondary endpoint results, and the FDA's interpretation of those results, could reach a different conclusion than our review of those data. Based upon negative or inconclusive results, or any interpretation or determination by the FDA that our clinical trial data have produced inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and which may mean our current data are not sufficient to support regulatory approval on a timely basis or at all. In addition, any NDA we submit may not be filed for review by the FDA, resulting in a refuse to file communication, or the FDA's review, if filed, could result in issuance of a complete response letter. While we previously discussed our clinical trial design plans with the FDA, there is no guarantee that the clinical development we conducted will support regulatory approval. As a result, we cannot be certain that our past or future clinical trials or preclinical studies will be successful to advance Oxnimbi or any future product candidates to approval. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could also limit the prospects for regulatory approval Oxnimbi or any future product candidates in such indications. Any of these factors could affect our ability to obtain regulatory approval for Oxnimbi or any future product candidates on a timely basis or at all, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Development of combination therapies may present more or different challenges than development of single agent therapies.

Oxnimbi is a fixed-dose combination drug product. The development of combination therapies may be more complex than the development of single agent therapies and generally requires that sponsors demonstrate the contribution of each component to the claimed effect and the safety and efficacy of the combination as a whole. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's current or future approval standards required for combination products. For example, under the "combination rule," the FDA may not file or approve a fixed-dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. To satisfy these requirements, the FDA typically requires a clinical factorial study, designed to assess the effects attributable to each drug in the combination product. This is particularly true when the ingredients are directed at the same sign or symptom of the disease or condition. The FDA has accepted a variety of approaches to satisfy the combination rule. The FDA has also stated that it may be possible to use other types of clinical and nonclinical data and mechanistic information available to demonstrate the contributions of the individual active ingredients to the effect of the combination. While we have provided clinical data to the FDA from our completed clinical trials suggesting that aroxybutynin or atomoxetine monotherapy would not be as effective as the combination, the FDA could later decide that a factorial trial is needed to support a marketing approval of Oxnimbi.

In addition, to the extent we choose to develop and commercialize a product candidate for use in patients receiving an already approved therapy, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to the approved therapy could have an adverse impact on us. Moreover, the applicable requirements for approval of a combination therapy may differ from country to country. In the event that Oxnimbi or any future product candidates were to fail to demonstrate sufficient safety and efficacy or establish its contribution to the claimed effects of a combination product, we would need to identify alternatives. In the event we are unable to do so or are unable to do so on commercially reasonable terms, our business and prospects would be materially harmed.

The use of Oxnimbi or any future product candidates, could be associated with side effects, such as insomnia, AEs or other properties or safety risks that could delay or prevent regulatory approval, limit our market acceptance, if approved, or result in significant negative consequences following marketing approval.

As is the case with pharmaceuticals generally, there are side effects and AEs associated with the use of Oxnimbi, and it is likely that there may be side effects for any future product candidates. In our Phase 3 clinical trials, dry mouth, insomnia and nausea were the most common treatment-related AEs. Even if approval is received, such side effects, if observed on a larger scale, may prevent widespread use of Oxnimbi, which would limit market acceptance and the commercial profile of Oxnimbi and may make Oxnimbi an undesirable drug for a large part of the patient population. Consequently, these side effects may significantly limit our market opportunity. While we believe our Phase 3 clinical trials (LunAIRo and SynAIRgy) were completed successfully, we may fail to demonstrate with substantial evidence to the satisfaction of the FDA or comparable foreign regulatory authorities that Oxnimbi or any future product candidates are safe and effective for their intended uses. Results of our clinical trials could reveal a high and

unacceptable severity and prevalence of side effects or unexpected characteristics. There can be no assurance that patients will not experience treatment-related SAEs, even after marketing approval, if achieved. Undesirable side effects caused by Oxnimbi or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or the denial of regulatory approval by the FDA or other comparable foreign authorities. If drug-related SAEs are observed, our trials could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny the approval for Oxnimbi or any future product candidates for any or all targeted indications. The potential for drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we encounter safety or efficacy problems with Oxnimbi or any future product candidates, our business could be significantly harmed. Oxnimbi or any future product candidates may fail to show the desired safety profiles and efficacy results despite progressing through clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulatory agencies may require us, to conduct additional clinical trials or nonclinical studies. Moreover, if Oxnimbi or any future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for such product candidate, if approved. Unacceptable enhancement of certain toxicities may be seen when Oxnimbi or any future product candidates are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our clinical trials. Many pharmaceuticals that initially showed promise in early-stage testing for patient treatment have later been found to cause side effects that prevented further development of such pharmaceuticals.

It is possible that as we continue to test Oxnimbi or any future product candidates in larger, longer and more extensive clinical trials, or after such product candidates are made available to patients on a commercial scale, if approved, illnesses, injuries, discomforts and other AEs that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. In many cases, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. For example, there are reports in the literature about the abuse potential of oxybutynin, a compound that is in the same class as aroxybutynin, but no abuse events have been reported in any clinical trial of Oxnimbi. Moreover, labeling for atomoxetine carries a boxed warning for increased risk of suicidal ideation in children and adolescents. In addition, the labeling contains warnings related to severe liver injury, serious cardiovascular events, increases in blood pressure or heart rate, emergence of new psychotic or manic symptoms, the appearance or worsening of aggressive behavior or hostility and allergic reactions, including anaphylactic reactions, amongst other warnings.

These, as well as additional unexpected side effects, could occur in those receiving Oxnimbi, which could result in similar warnings, including a boxed warning, appearing in the product labeling for Oxnimbi, if approved, or materially harm our ability to obtain approval of Oxnimbi. Further, if in the future Oxnimbi is approved, and in particular for pediatric use, a similar boxed warning found in atomoxetine could appear in the product labeling for Oxnimbi. In addition, the FDA could require contraindications for Oxnimbi in specific populations, which could limit the eligible OSA population for Oxnimbi and adversely impact patient and medical community acceptance of Oxnimbi for OSA.

Additionally, if Oxnimbi or any future product candidates receive marketing approval, and we or others later identify undesirable side effects or interactions making those product candidates less effective, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace;
- regulatory authorities may withdraw approvals or change their approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require labeling changes, including additional warnings on the label, boxed warnings or additional boxed warning content, issuance of safety alerts or press releases, or limit access to that product;
- we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients and other elements to assure safe use, or comparable foreign risk management approaches;
- we may be required to change the way the product is administered;
- we may be required to conduct additional clinical trials or conduct additional post-marketing studies or surveillance;
- we may receive FDA Form 483s, untitled letters, warning letters or other types of enforcement-related letters or may become subject to product recalls or product seizures;

- we could be subject to fines, injunctions or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- sales of the product may decrease significantly or the product may become less competitive, physicians may not recommend the products to patients and our reputation may suffer.

We believe any of these events could prevent us from achieving or maintaining market acceptance of Oxnimbi or any future product candidates, if approved, and could significantly harm our business, results of operations, and prospects.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for Oxnimbi or any future product candidates, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, safety and efficacy of such product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In addition, in many countries, securing pricing and reimbursement approval (or coverage and formulary placement) is important to achieving broad market access and may significantly delay or limit commercial launch and uptake even after marketing approval. In some cases, the price that we intend to charge for Oxnimbi or any future product candidates is also subject to approval.

Regulatory authorities in jurisdictions outside of the United States and the European Union ("EU") also have requirements for approval for product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of Oxnimbi or any future product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of Oxnimbi or any future product candidates will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

We submitted a NDA under Section 505(b)(2) regulatory pathway to seek regulatory approval of Oxnimbi, but if the FDA concludes that our marketing application no longer qualifies for the Section 505(b)(2) regulatory pathway, then our application may not be accepted by the FDA for review and approval may be delayed.

We submitted a NDA to seek FDA approval for Oxnimbi for OSA through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, and permits the submission of an NDA where at least some of the information required for approval comes from nonclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product.

Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for Oxnimbi by potentially decreasing the amount of nonclinical or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, the time and financial resources required to obtain FDA approval for Oxnimbi, and complications and risks associated with advancing the development of Oxnimbi, would likely substantially increase. The FDA could require additional information or data to sufficiently demonstrate safety and efficacy to support approval. If the FDA determines Oxnimbi does not meet the requirements of Section 505(b)(2), or that additional information is needed to support a marketing application for Oxnimbi, we could experience delays in obtaining marketing approval.

We have received Fast Track Designation for Oxnimbi for OSA and may seek such designation for other future product candidates, but we might not receive such designations, and even if we do, such designations may not actually lead to a faster development or regulatory review or approval process and does not increase the likelihood that Oxnimbi or any future product candidates which may receive Fast Track designation will receive regulatory approval.

If a product candidate is intended for the treatment of a serious condition and preclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation, which is intended to expedite or facilitate the process for reviewing such product candidates. The sponsor of a Fast Track product candidate has

opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review if the relevant criteria are met. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

In May 2022, we received Fast Track designation for Oxnimbi for the treatment of OSA, and we may seek Fast Track designation for any future product candidates, but we might not receive such designations from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA product development timeframes. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. The EMA has a similar program called Priority Medicine ("PRIME") designation. The purpose of this program is to enhance support for the development of medicinal products that target an unmet medical need. PRIME provides enhanced interaction and early dialogue between the EMA and developers of promising medicinal products to optimize generation of robust data on the benefits and risks of such medicinal products and may enable accelerated assessment of centralized marketing authorization applications for product participating in the PRIME scheme. Participation in PRIME does not, however, limit the obligations that must be fulfilled for grant of a related marketing authorization. We may seek PRIME designation for Oxnimbi or any future product candidates, but might not receive such designations. Even if we receive PRIME designation, there is no guarantee of grant of marketing authorization at all or within any specific timeframe.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable and the FDA or comparable foreign authorities may disagree with our regulatory plans, and if we are ultimately unable to obtain regulatory approval for Oxnimbi or any future product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market Oxnimbi or any future product candidates in the United States until we receive regulatory approval of an NDA from the FDA. The FDA and other regulatory authorities may delay, limit or deny approval of Oxnimbi or any future product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other regulatory authorities that Oxnimbi or any future product candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with our pathway selection of the Section 505(b)(2) pathway, the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other regulatory authorities may not find the data from nonclinical studies and clinical trials sufficient to demonstrate that the benefits of Oxnimbi or any future product candidates outweigh their safety risks;
- the FDA or other regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials or may not accept data generated at our clinical trial sites;
- the data collected from nonclinical studies and clinical trials of Oxnimbi or any future product candidates may not be sufficient to support the submission of an NDA or other application for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional nonclinical studies or clinical trials, modifications or limitations on approved labeling, or distribution and use restrictions;
- the FDA or other regulatory authorities may require development of a REMS, or risk management plan, as a condition of approval;

- the FDA or other regulatory authorities may raise questions regarding our to-be-marketed formulation or identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or other regulatory authorities may change their approval policies or adopt new regulations; and
- the FDA or other regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory authorities may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application.

Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory authorities for obtaining approval, and we may not be able to obtain regulatory approval even if we comply with all FDA requests.

Moreover, principal investigators for our clinical trials may serve and have served 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. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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, and may ultimately lead to the denial of marketing approval of Oxnimbi or any future product candidates.

In addition, the FDA or other regulatory authorities may approve Oxnimbi or any future product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, such as a boxed warning, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS or comparable foreign risk management approaches. The FDA or other regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of Oxnimbi or any future product candidates.

Changes in the manufacturing process or formulation may result in additional costs or delay. If we or our CMOs are not able to successfully manufacture Oxnimbi or any future product candidates in sufficient quality and quantity, or if manufacturing changes are required, there could be adverse impacts to clinical development and timelines for Oxnimbi or any future product candidates and, if approved, to subsequent pre-commercialization and commercialization activities.

As product candidates progress through nonclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the manufacturing process, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, as well as, minimize costs and achieve consistent quality and results. Additionally, the need for other manufacturing changes may occur at any time. Such changes carry the risk that they will not achieve these intended objectives. Any such changes could cause Oxnimbi or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials, and limit our ability to rely on data from clinical trials conducted with an earlier version of our product candidate. This could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Oxnimbi or any future product candidates and jeopardize our ability to commercialize Oxnimbi or any future product candidates, if approved, and generate revenue. If we or our CMOs are not able to successfully manufacture Oxnimbi or any future product candidates in sufficient quality and quantity, the clinical development and timelines for Oxnimbi or any future product candidates and subsequent approval and commercialization could be adversely impacted.

We may not be successful in our efforts to identify and successfully research and develop additional product candidates and may expend our limited resources to pursue particular product candidates or indications while failing to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of commercial success.

Part of our business strategy involves identifying and developing new product candidates for sleep apnea and other sleep breathing diseases. The process by which we identify product candidates may fail to yield successful product candidates for a number of reasons, including:

- we may not be able to assemble sufficient resources to identify or acquire additional product candidates;

- competitors may develop alternative therapies that render new product candidates obsolete or less attractive;
- product candidates we develop or acquire may be covered by third-party intellectual property rights;
- new product candidates may, on further study, be shown to have limited to no efficacy, adverse side effects, toxicities, or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance;
- new product candidates may not be safe or effective;
- the market for a new product candidate may change so that the continued development of that product candidate is no longer reasonable; and
- we may not be able to produce new product candidates in commercial quantities at an acceptable cost, or at all.

We have limited financial and managerial resources. We are focused initially on Oxnimbi and, as a result, we may forego or delay pursuit of opportunities with other potential product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on Oxnimbi and any future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for Oxnimbi or any future product candidate, we may relinquish valuable rights to such product candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If clinical trials for Oxnimbi or any future product candidates are prolonged, delayed or suspended, we may be unable to obtain or seek regulatory approval for and commercialize Oxnimbi or any future product candidates on a timely basis, if at all, which would require us to incur additional costs and substantially harm our business.

Drug development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that Oxnimbi or any future product candidates are safe and effective for use in their target indications before we can obtain or seek regulatory approvals for their commercial sale. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. Delays or failures can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by regulatory authorities.

Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results.

We cannot predict whether we will encounter problems with any future clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- serious or unexpected side effects related to the product candidate being tested or in clinical trials of the same class of agents conducted by other companies;
- selection of doses that may be found suboptimal;
- slower than expected recruitment and enrollment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- lack of adequate funding to continue any of our clinical trials;
- changes to the clinical trial protocols;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure of our third-party vendors to perform manufacturing and distribution services in a timely manner or to sufficient quality standards and current good manufacturing practice ("cGMP");
- difficulties obtaining regulatory authorization to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

- reaching or failing to reach agreement on acceptable terms with prospective CROs, CMOs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- inability to generate sufficient nonclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- difficulties obtaining institutional review board ("IRB") approval or positive ethics committee opinions to conduct a clinical trial at a prospective site;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- lack of adequate funding to continue the clinical trials or nonclinical studies or costs being greater than we anticipate;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice ("GCP"), or other regulatory requirements, or being otherwise unwilling or unable to satisfy their contractual obligations to us in a timely manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines.

We cannot be certain whether our future clinical trials will proceed as planned, will need to be restructured or will be completed on schedule, if at all. Delays in the initiation, enrollment, or completion of our clinical trials may result in increased development costs for Oxnimbi or any future product candidates, and our financial resources may be insufficient to fund any incremental costs. If our clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of Oxnimbi or any future product candidates could be limited.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or relevant ethics committees of the institutions in which such trials are being conducted, or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols or informed consents, inspection of the clinical trial operations or trial site by the FDA or comparable foreign 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. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs, relevant ethics committees or competent authorities for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Additionally, we have, and may in the future utilize “open-label” clinical trial designs. An open-label clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results for Oxnimbi or any future product candidates when studied in a controlled environment with a placebo or active control.

If we encounter difficulties enrolling patients in clinical trials for Oxnimbi or any future product candidates, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of eligible patients who remain in the trials until their conclusion. We may not be able to initiate, continue or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for Oxnimbi or any future product candidates if we are

unable to locate, enroll and retain a sufficient number of eligible patients to participate in clinical trials for such product candidates. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the availability of new drugs or medical technologies approved for the indication the clinical trial is investigating;
- the availability of competing clinical trials for similar target populations;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies;
- the risk profile of Oxnimbi or any future product candidates, including any serious safety risks that may be identified;
- patient eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit qualified clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of Oxnimbi or any future product candidates or completion of our trials;
- the severity of the disease under investigation; and
- other factors outside of our control, such as global economic conditions and volatility in the credit and financial markets and inflationary pressures.

Delays in the completion of any clinical trial of Oxnimbi or any future product candidates will increase our costs, slow down our product candidate development and regulatory approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of Oxnimbi or any future product candidates. In addition, even if Oxnimbi or any future product candidate is approved, these and other factors may impact its market adoption.

In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and nonclinical studies. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would harm our business and result in the delay of completion of such trials beyond our expected timelines.

Interim, "top-line" 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 preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or top-line data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line 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, top-line data should be viewed with caution until the final data is available.

From time to time, we may also disclose interim data from our nonclinical studies and 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, study population size, safety database size, interpretations of data or analyses or may interpret or weigh the importance of data or treatment effect differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. For example, our primary indication of focus is OSA which does not have well-established therapeutic endpoints that have been accepted by the FDA in the past. 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 stockholders may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached by such data, our ability to obtain approval for and commercialize Oxnimbi or any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not be able to file INDs or IND amendments, or comparable foreign applications, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed.

We may not be able to file investigational new drug applications ("INDs"), or comparable foreign applications, for Oxnimbi or any future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND, or comparable foreign applications, will result in the FDA or other regulatory authorities allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, or comparable foreign applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or comparable foreign applications. Any failure to file INDs, or comparable foreign applications, or submit our clinical trial protocols to regulatory authorities for review on the timelines we expect may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We have conducted and may in the future conduct certain of our clinical trials outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We conducted our SynAIRgy clinical trial with some study sites located in Canada and we, or our current or any future collaborators, may in the future conduct one or more of our clinical trials outside the United States. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. If access to clinical trial sites or documentation is delayed or restricted, including for geopolitical reasons, the FDA may not accept such data in support of an IND or marketing application which would adversely affect our development and approval plans. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. In addition, the FDA recently signaled increased scrutiny of foreign clinical trial data submitted in support of marketing applications, indicating plans for increased foreign site inspections and increased transparency of inspection results. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of Oxnimbi or any future product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of such product candidate. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and AEs;
- diminished protection of intellectual property in some countries; and

- public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial, limit or restrict access to foreign trial sites and documentation and evaluate resulting data.

Risks Related to Development and Commercialization of Oxnimbi and Any Future Product Candidates

The marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approval for the commercialization of Oxnimbi. Furthermore, if there are delays in obtaining regulatory approvals, we may not be able to commercialize our products, may lose competitive lead time and our ability to generate revenues will be materially impaired.

The activities associated with Oxnimbi's development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, sampling, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States, and by the EMA and other comparable regulatory authorities in other countries. Failure to obtain marketing approval for Oxnimbi will prevent us from commercializing Oxnimbi in a given jurisdiction. We have not received approval to market Oxnimbi from regulatory authorities in any jurisdiction, and it is possible that we may be unable to do so.

Although some members of our management team have experience in submitting and supporting the applications necessary to gain marketing approvals, we as an organization expect to rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of extensive information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. This includes the submission of stability data supporting the labeled expiry period and shelf life of the product. Although FDA guidelines typically require at least 12 months of long-term and six months of accelerated stability data for each registration batch at the time of an NDA filing, we submitted our NDA with six months of stability data, which, if approved, will provide us with six months of expiry dating. Upon potential approval, we expect to have 12 months of stability data, which would allow us to extend the expiry dating to at least 24 months. However, if the 12 month data does not meet the agreed specifications, we will not be able to extend the expiry dating beyond six months. Furthermore, Oxnimbi may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics or may have manufacturing data FDA views as inadequate to support filing and review of our NDA and that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidate involved.

If we experience delays in obtaining approval or if we fail to obtain approval of Oxnimbi or any future product candidates we may develop, the commercial prospects for those product candidates and our ability to generate revenues will be materially impaired and we may lose competitive lead time as similar products enter the market.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, changes in FDA leadership, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, EMA and other comparable regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional nonclinical, clinical or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The FDA may also require an advisory committee to deliberate on the adequacy of the safety and efficacy data. The opinion of an advisory committee, if solicited by the FDA, although not binding, may have a significant impact on our ability to obtain marketing approval of Oxnimbi or any future product candidates based on our completed clinical trials, as the FDA often adheres to an advisory committee's recommendations.

If we experience delays in obtaining approval or if we fail to obtain approval of Oxnimbi, the commercial prospects for Oxnimbi may be harmed, and our ability to generate revenues will be materially impaired.

We are in the process of building our marketing, sales and other commercial capabilities. If we are unable to establish effective sales and marketing capabilities or enter into agreements with third parties to market and sell Oxnimbi, if approved, we may not be successful in commercializing Oxnimbi and may be unable to generate any product revenue.

We are in the process of building our marketing, sales and other commercial capabilities. Even if Oxnimbi or any future product candidates ultimately receive regulatory approval, to achieve commercial success, among other factors, we must build a marketing and sales organization, with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or we must collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company with the marketing, sale or distribution of biopharmaceutical products and there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. Factors that may inhibit our efforts or third-party efforts to commercialize Oxnimbi or any future product candidates, if approved, on our own include:

- our ability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our ability to effectively manage a geographically dispersed sales and marketing team;
- the ability of sales personnel to generate sufficient sales leads and obtain access to physicians to prescribe Oxnimbi or any future product candidates, if approved, or to educate adequate numbers of patients on the benefits of Oxnimbi or any future product candidates, if approved;
- any views or opinions expressed by OSA community organizations about the efficacy of Oxnimbi, if approved, or any future approved product candidates;
- our ability to obtain adequate coverage by and reimbursement from third-party payors and governmental agencies; and
- any unforeseen costs and expenses in building an internal sales and marketing organization.

As we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or profitability could be impacted and could be lower than if we were to market and sell Oxnimbi ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market Oxnimbi or any future product candidates, if approved, or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market Oxnimbi, or any future product candidates, if approved, effectively. Furthermore, if the commercial launch of Oxnimbi or any future product candidates for which we enter into arrangements for sales, marketing and distribution services is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot maintain or reposition these arrangements. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing Oxnimbi, if approved, and would incur significant additional losses.

We may never obtain approval to commercialize Oxnimbi or any future product candidates outside the United States, which could limit our ability to recognize the full market potential of Oxnimbi or any future product candidates and could materially impair our ability to generate revenues.

In order to market and sell Oxnimbi or any future product candidates in the EU, or other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize Oxnimbi or any future product candidates in multiple jurisdictions, which could materially impair our ability to generate revenue.

The commercial success of Oxnimbi will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Oxnimbi may not be commercially successful. Even if Oxnimbi receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of Oxnimbi will depend significantly on the broad adoption and use of the product by these individuals and organizations for approved indications. The degree of market acceptance of Oxnimbi will depend on a number of factors, including:

- our ability to educate the OSA medical community, patients and payors on the benefits of Oxnimbi, if approved, and convince physicians, patients who are unable to use or get consistent benefits from PAP and payors that Oxnimbi is an attractive alternative, if approved, to other treatment options;
- demonstration of Oxnimbi's clinical efficacy and safety, including as compared to any more-established products and devices;

- Oxnimbi's potential inability to reduce the symptoms of OSA, such as sleepiness, while reducing AHI for certain patients, and our inability to determine the reduction in apnea hypopnea index ("AHI") needed to improve said symptoms;
- in deciding whether to use Oxnimbi, patients may focus more on subjective outcomes, such as reduction in fatigue, sleepiness or other symptoms of OSA, rather than on objective outcomes, such as reduction in AHI, and may be dissatisfied if they do not perceive their fatigue, sleepiness or other symptoms of OSA, as being reduced even when there are reductions in the patient's AHI;
- the ability of Oxnimbi to cause side effects, such as insomnia;
- the indications for which Oxnimbi is approved, including mild, moderate and severe OSA;
- that some physicians may not prescribe Oxnimbi to patients with mild OSA who do not experience sleepiness, fatigue and similar symptoms of OSA, and such patients with mild OSA may also be reluctant to seek treatment;
- the limitation of our targeted patient population and other limitations or warnings, including boxed warnings, contained in any FDA-approved labeling;
- if PAP is considered by patients to be a more effective treatment than Oxnimbi, patients may opt for PAP over Oxnimbi despite it being less comfortable and convenient;
- the reluctance of patients to take an oral drug with potential adverse effects and side effects, as opposed to using PAP;
- acceptance of a new drug for OSA, especially for severe OSA, by healthcare providers and their patients;
- publicity concerning Oxnimbi or competing drugs and treatments;
- the pricing and cost-effectiveness of Oxnimbi, as well as the cost of treatment with Oxnimbi in relation to alternative treatments and therapies;
- physicians' inclinations to prescribe conventional existing treatments of OSA such as PAP, glucagon-like peptide-1 ("GLP-1")/glucose-dependent insulinotropic polypeptide ("GIP") agonists and Inspire®, a hypoglossal nerve stimulation system, by Inspire Medical Systems, Inc. ("Inspire"), or potential to prescribe an expanding pipeline of oral incretin therapies targeting OSA, such as Eli Lilly and Company's Foundayo® (orforglipron);
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of Oxnimbi, and the prevalence and severity of any adverse effects;
- the timing of market introduction, as well as availability, safety and efficacy of competitive drugs or devices;
- the effectiveness of our or any potential future collaborators' sales and marketing strategies; and
- potential product liability claims.

Oxnimbi has been shown to cause undesirable side effects, such as its ability to cause or worsen insomnia. Even after receiving approval, such side effects may prevent widespread use of Oxnimbi which will limit the commercial profile of Oxnimbi and may make Oxnimbi an undesirable drug for a large part of the patient population. Consequently, it may significantly limit our market opportunity.

In addition, while Oxnimbi may reduce the AHI, we have observed that some patients still experience symptoms of OSA, such as sleepiness. Such patients may underestimate the long-term life-threatening consequences of OSA and stop taking Oxnimbi, if approved. This may cause long-term patient compliance to be significantly lower than we estimate and it may limit our market opportunity and adversely impact our business and results of our operations.

If Oxnimbi is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful. Our failure to achieve market acceptance or commercial success would adversely affect our business prospects.

We currently compete and will in the future continue to compete with other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results.

The pharmaceutical, biotechnology and medical device industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated and will continue to dedicate significant resources to promoting their products or developing new products or methods to treat OSA and related sleep breathing diseases. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions that may be active in research in our target indications and could be in direct competition with us.

We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and identifying and in-licensing intellectual property related to new product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. To the extent we expand internationally, we will face additional competition in geographies outside the United States.

We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan.

If we receive marketing approval for Oxnimbi, we will consider our primary competition to be PAP, which is the typical first-line therapy for patients diagnosed with moderate to severe OSA. Two leading PAP manufacturers are ResMed Corp. and Philips N.V. (through its subsidiary Respironics Inc.). We will additionally face competition from surgically implanted devices, such as Inspire® by Inspire, a hypoglossal nerve stimulation system that is targeted to a subset of OSA patients. In addition, we may also compete with invasive surgical treatment options such as uvulopalatopharyngoplasty and maxillomandibular advancement and robotic tongue reduction surgery. Most of the other OSA treatments that we will compete against, such as PAP, oral devices, or the Inspire® device, already have a substantial penetration into the OSA treatment market. In addition, there are also several programs in clinical and nonclinical development to treat OSA by pharmaceutical companies including Bayer AG, Incannex Healthcare Ltd. and Mosanna Therapeutics. Additionally, we may face competition from GLP-1 agonists or GLP-1/GIP co-agonists for OSA in patients with a higher body mass index as excess body weight can be a contributing factor in the etiology of OSA. For example, in December 2024, the FDA approved Eli Lilly and Company's Zepbound® (tirzepatide) GLP-1 product for the treatment of moderate-to-severe OSA in obese adults in combination with a reduced-calorie diet and increased physical activity. In addition, in November 2026, Eli Lilly and Company announced that its oral GLP-1 receptor agonist, Foundayo® (orforglipron), demonstrated positive results in its Phase 3 ATTAIN-OSA trial in patients with moderate-to-severe OSA and who are obese or overweight.

Some of the companies against which we will compete may have competitive advantages with respect to primary competitive factors in the OSA treatment market, including:

- more widely accepted products and first-in-line therapies for OSA;
- more effective marketing to and education of patients, physicians and sleep centers;
- improved reliability, safety and effectiveness, or the perception of such factors;
- greater company, product and brand recognition;
- more sales force experience and greater market access;
- better quality or larger volume of clinical data;
- more effective clinical training teams;
- greater capital resources; and
- more effective pricing and revenue strategies.

Our competitors may also obtain patent protection, regulatory exclusivities or regulatory approval and commercialize products more rapidly than we do, which may impact future sales of Oxnimbi, if approved. Our profitability and financial position will suffer even if Oxnimbi receives regulatory approval but cannot compete effectively in the marketplace.

Even if we are able to commercialize Oxnimbi, it may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize

Oxnimbi will depend in part on the extent to which reimbursement for Oxnimbi and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers, decide which medications they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive or more effective product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Oxnimbi and any future product candidates.

Obtaining and maintaining coverage and reimbursement can be time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often time consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be secured or applied consistently. Furthermore, rules and regulations regarding reimbursement change frequently and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation, regulation or administrative action, either in the United States or abroad. 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, Oxnimbi may lose any marketing approval that may have been obtained, and we may not achieve or sustain profitability, which would adversely affect our business.

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 has and will continue to put pressure on the pricing and usage of Oxnimbi or any future product candidates, if approved in these jurisdictions. 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 our products. Accordingly, in markets outside the United States, if any, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Oxnimbi or any future product candidates and may affect the prices we may set.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services ("HHS"), the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders from President Trump, proposed rulemaking from CMS or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions, for example, include (i) directives to reduce agency workforce; (ii) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending; (iii) eliminating the Biden administration's executive order that directed HHS to establish an artificial intelligence task

force and develop a strategic plan; (iv) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (v) imposing tariffs on imported pharmaceutical products; (vi) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans; and (vii) as part of the Make America Healthy Again Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion in the Inflation Reduction Act of 2022, and reduce Medicaid enrollment and funding. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize Oxnimbi or any future product candidates.

If the market opportunity for Oxnimbi is smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The incidence and prevalence for target patient populations of Oxnimbi have not been established with precision. Our estimate of the number of people who have OSA is based on our estimates and third party studies. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. Further, new trials or information may change the estimated incidence or prevalence of OSA. If approved, the total addressable market opportunity will ultimately depend upon, among other things, the patient criteria included in the final label, the indications for which Oxnimbi is approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with OSA for which Oxnimbi may be approved as a treatment may turn out to be lower than expected, including as a result of the FDA's interpretation of the clinical meaningfulness of our drug on certain patient populations, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Oxnimbi is our sole clinical product candidate and therefore our business is dependent on the potential market opportunity for Oxnimbi in OSA. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for Oxnimbi or any future product candidates we may develop may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If any product liability lawsuits are brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of Oxnimbi.

If Oxnimbi is approved by regulatory authorities and introduced commercially, we face an inherent risk of product liability lawsuits. Product liability claims may be brought against us or our partners by patients, healthcare providers or others using, administering or selling Oxnimbi, if approved. If we cannot successfully defend against any such claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Oxnimbi, if approved;
- injury to our reputation and significant negative media attention;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- product recalls or a change in the indications for which Oxnimbi may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize Oxnimbi, if approved; and

- a decline in our stock price.

If Oxnimbi is approved for commercial sale, we will be highly dependent upon consumer perceptions of our company and the safety and quality of Oxnimbi. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if Oxnimbi or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients, which could lead to the recall or market withdrawal. In addition, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of Oxnimbi or any similar products distributed by other companies could have a material adverse impact on our results of operations.

Prior to commercialization of our Oxnimbi, if approved, we will need to purchase additional insurance coverage. We may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our development and commercialization efforts. A successful product liability claim, or series of claims brought against us, particularly if judgments exceed our available insurance coverage, could decrease our cash resources and adversely affect our business, financial condition and results of operations.

Off-label use or misuse of Oxnimbi, if approved, may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as Oxnimbi or any future product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If Oxnimbi is approved by the FDA, or any jurisdiction, we, or any contract sales force we may recruit, may only promote or market Oxnimbi in a manner consistent with FDA-approved labeling. We will train our marketing and sales force against promoting Oxnimbi for uses outside of the approved indication for use, known as "off-label uses." We cannot, however, prevent a physician from using Oxnimbi off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of Oxnimbi for indications other than approved by the FDA may not effectively treat such conditions. Any such off-label use of Oxnimbi could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use Oxnimbi for these uses for which it is not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Further, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. Further, FDA's OPDP actively surveils promotional labeling and advertising, including digital promotional activities. In the current administration, the FDA has increased its enforcement scrutiny over prescription drug advertising, particularly direct-to-consumer product promotion and advertising. Any materials that are found by FDA to be false, misleading, or to promote unapproved uses, minimize risk information, or to promote unsubstantiated claims can lead to enforcement actions and could necessitate corrective communications. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. OPDP has increased efforts to monitor promotional activities, particularly those directed to consumer and patient audiences. If we cannot successfully manage the promotion of Oxnimbi or any future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we fail to develop and commercialize other product candidates beyond Oxnimbi, we may be unable to grow our business.

Although the development and commercialization of Oxnimbi is our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of potential future product candidates designed to treat additional types of sleep apnea and other sleep breathing diseases. We may also choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from types of sleep apnea and other sleep breathing diseases. These other product candidates may require additional, time-consuming and costly development efforts prior to commercial sale, including nonclinical studies, clinical trials and approval by the FDA or applicable foreign regulatory authorities. All such potential future product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace or be more effective than other commercially available alternatives.

Risks Related to Third Parties

We have engaged in a strategic disposition and our business may suffer if we fail to realize the anticipated benefits from such disposition.

In April 2026, we sold to Shionogi (i) all of our membership interests in SASS, and (ii) certain intellectual property and other assets directly related to SASS's development programs, including the asset purchase and license agreement (the "Desitin APA") with

Desitin Arzneimittel GmbH and Cereus Pharma AB, pursuant to the MIPA (the "SASS Disposition"). In addition, at the closing of the SASS Disposition, we converted certain exclusive licenses to our intellectual property relevant to the use of compounds in sleep disorders that were within the scope of SASS's pre-closing activities (each, a "JV Compound") and in existence as of the effective date of the MIPA into perpetual, irrevocable, non-exclusive and royalty-free licenses solely with respect to a specified set of products that incorporate one or more JV Compound.

While we have agreed to only limited indemnification and other obligations in connection with the SASS Disposition, there can be no assurance that we will not be subjected to indemnification claims or other liabilities in connection with the SASS Disposition.

Further, achieving the anticipated benefits of the SASS Disposition is subject to a number of uncertainties. There can be no assurance that we will realize the full benefits of strategic focus, cost savings and operating efficiencies that we currently expect from the SASS Disposition or that such benefits will be achieved within anticipated timeframes. Failure to achieve these anticipated benefits could result in increased costs and diversion of management's time and energy and could materially adversely affect our business, financial position, results of operations and cash flows.

Our existing agreements contain, and any agreements that we may enter into in the future may contain, non-compete and other covenants that restrict our product development and commercialization activities and other provisions that may expose us to significant potential liability.

Certain of our existing agreements contain covenants that restrict our product development or future business efforts and impose, among other things, limitations on our ability to license Oxnimbi or any future product candidates to third parties and restrictions on our ability to compete. In particular, the MIPA provides that we are subject to a five year worldwide non-competition obligation in relation to the exploitation of any product containing a JV Compound for the treatment, prevention or mitigation of sleep disorders. Because of these restrictive covenants, we may not be able to further develop certain potential future product candidates, which could impact the growth of our business. These restrictive covenants also may preclude us from pursuing development of additional product candidates within our area of expertise, which could impair our ability to execute our strategy and grow our business.

We may seek to establish additional strategic relationships, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

We may seek to establish additional strategic relationships, such as collaborations, joint ventures, license agreements and other similar arrangements, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans. Whether we 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 own evaluation of a potential collaboration. Factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for Oxnimbi or any future product candidates. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. Collaborations 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 potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program of one or more of our other development programs, delay our 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 capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop Oxnimbi or any future product candidates or bring them to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. 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 Oxnimbi or any future product candidates. Our ability to generate revenue from these arrangements will depend on any future

collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

Collaborations involving Oxnimbi or any future product candidates would pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or at all;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of Oxnimbi or any future product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Oxnimbi or any future product candidates if the collaborators believe that 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 collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to Oxnimbi or any future product candidate that achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of Oxnimbi or any future product candidates, might lead to additional responsibilities for us with respect to Oxnimbi or any future product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly enforce, maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding any out-licensed product candidates;
- we may be required to invest resources and attention into such collaboration, which could distract from other business objectives;
- disputes may arise between the collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations;
- collaboration agreements may not lead to development or commercialization of Oxnimbi or any future product candidates in the most efficient manner or at all;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and

- collaborations may be terminated, including for the convenience of the collaborator, prior to or upon the expiration of the agreed upon terms and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of Oxnimbi or any future product candidates.

Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to Oxnimbi or any future product candidates, could delay the development and commercialization of such product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have relied on, and we expect to continue to rely on, CMOs to produce Oxnimbi or any future product candidates. Our CMOs may experience manufacturing difficulties due to the ongoing effects of inflationary pressures, resource constraints, labor disputes or unstable political environments, which could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and significantly impact our ability to develop, obtain regulatory approval for, or market Oxnimbi and any future product candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of Oxnimbi or any future product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to continue to rely for the foreseeable future, on CMOs to supply Oxnimbi or any future product candidates. Reliance on CMOs entails risks to which we would not be subject if we manufactured Oxnimbi or any future product candidates ourselves, including:

- the failure of the CMO to manufacture Oxnimbi or any future product candidates according to our schedule, or at all, including if our CMOs give greater priority to the supply of other products over Oxnimbi or any future product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the failure of the CMO to maintain adequate quality control, quality assurance and qualified personnel;
- the reduction or termination of production or deliveries by suppliers or the raising of prices or renegotiation of terms;
- the breach by the CMOs of our agreements with them;
- the failure of CMOs to comply with applicable regulatory requirements;
- the failure of the CMO to manufacture Oxnimbi or any future product candidates according to our specifications and the FDA and comparable foreign regulatory authorities' strict regulatory requirements;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of manufacturing agreements by CMOs, at a time that is costly or inconvenient to us.

If we do not maintain relationships with our current and future CMOs, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for Oxnimbi or any future product candidates and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us.

We have relied on one CMO to manufacture and supply Oxnimbi for our completed clinical trials. If Oxnimbi receives marketing approval, our current and future CMOs may be required to substantially increase their production and optimize their manufacturing processes. We have entered into preliminary commercial manufacturing and supply service agreements with certain of our CMOs for the supply, manufacture and packaging of Oxnimbi, but do not have any agreements with our CMOs for work related to the synthesis of the API for future use. If such CMOs are unable to produce increased amounts of aroxybutynin and atomoxetine, while maintaining the same quality and without making changes to the formulation of Oxnimbi that could require approval by the FDA, then we may not be able to meet market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations. Additionally, if our CMO for Oxnimbi were to experience any cGMP compliance deficiencies that impacted the quality of Oxnimbi or their ability to scale and produce Oxnimbi for us, our ability to timely scale and commercialize Oxnimbi could be adversely affected. For example, our CMO previously received inspection observations of noncompliance on a Form FDA-483 and while those deficiencies have now been resolved, there may be other similar events in the future. If that occurs and our CMO is not able to successfully resolve those findings with the FDA, delays or setbacks in its manufacturing operations could adversely affect our ability to scale and commercialize Oxnimbi.

The FDA and other foreign regulatory authorities require manufacturers to register their manufacturing facilities. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of Oxnimbi or any future product candidates, or if it withdraws any such approval in the future, or if our suppliers or CMOs decide they no longer want to supply or manufacture for us, or if we choose to relocate manufacturing to another CMO, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop and obtain regulatory approval for Oxnimbi and any future product candidates.

The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMP and other applicable laws. We, our CMOs, any future collaborators and their CMOs could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. CMOs may face manufacturing or quality control problems causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Despite our efforts to audit and verify regulatory compliance, one or more of our CMOs or third-party vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Any failure to comply with cGMP requirements or other FDA and foreign regulatory authority requirements may result in shutdown of the CMO or third-party vendor or invalidation of drug product lots or processes and could adversely affect our clinical research activities and our ability to develop Oxnimbi or any future product candidates and market our products following approval, if obtained. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market Oxnimbi or any future product candidates, if approved.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing and practices, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. For example, we are currently working to validate our analytical methods and process controls needed to reproducibly produce drug product that meets commercial specifications. Furthermore, if contaminants are discovered in our supply of Oxnimbi or any future product candidates or in their manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Additionally, our manufacturers may experience manufacturing difficulties due to inflationary pressures, resource constraints, labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide Oxnimbi or any future candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Our current and anticipated future dependence upon others for the manufacture of Oxnimbi and any future product candidates may adversely affect our future profit margins and our ability to develop Oxnimbi or any future product candidates and commercialize any products that receive regulatory approval on a timely basis.

Our employees, contractors and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, partners or contractors, including principal investigators, CMOs, CROs, consultants and vendors. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign authorities, to comply with federal, state or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us, or failure to comply with comparable foreign requirements. 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, the creation of fraudulent data in our clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. In addition, our reputation may be harmed if any of our employees, directors, independent contractors, principal investigators or consultants are found to have been involved in similar misconduct outside of their services to our company. It is not always possible to identify and deter misconduct, 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 comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on

our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, debarment, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of Oxnimbi or any future product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research, commercial, sales, vendor, purchase or clinical trial agreements, including the BWH License and the MIPA, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, rights to receive milestones, royalties or other payments, the approach for regulatory approvals or commercialization strategy. Any disputes, delays or commercial conflicts could lead to the termination of agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

We have relied on third parties to conduct our clinical trials and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize Oxnimbi or any future product candidates and our business could be substantially harmed.

We have previously relied on, and intend to continue relying on, third parties, including independent clinical investigators and CROs, to conduct certain aspects of our clinical trials. We controlled or will control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data.

We, our investigators and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. Upon inspection, such regulatory authorities may determine that our clinical trials do not comply with the GCP regulations. If we or any of the study sites or these CROs fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing products. Our failure or any failure by our investigators or CROs to comply with these regulations or to recruit a sufficient number of patients may require us to terminate study sites, add additional study sites, or repeat clinical trials, which would delay the regulatory approval process. For example, in the past, we have had to terminate two study sites due to noncompliance with our study protocols or GCP. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Moreover, our business may be implicated if any of our investigators or CROs violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws and foreign equivalents.

Our investigators and CROs are not our employees, and, except for remedies available to us under our agreements with such investigators and CROs, we cannot control whether or not they devote sufficient time and resources to our nonclinical and clinical programs. These investigators and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If our investigators and CROs 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 for or successfully commercialize Oxnimbi or any future product candidates. As a result, our financial results and the commercial prospects for Oxnimbi and any future product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our investigators and CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our investigators and CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding investigators or CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new investigator or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our investigators and CROs,

we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, prospects, financial condition, and results of operations.

We may also rely on individual investigators or academic and non-academic institutions to conduct investigator-sponsored clinical trials relating to Oxnimbi or any future product candidates. We will not control the design or conduct of these investigator-sponsored trials, and it is possible that the FDA or comparable foreign regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of Oxnimbi or any future product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of Oxnimbi or any future product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, enforce or protect intellectual property rights related to Oxnimbi or any future product candidates or technology, we may not be able to compete effectively in our market.

We currently rely upon a combination of patents, registered trademarks and trademark applications, trade secret protection, other intellectual property rights, as well as contractual protections such as confidentiality agreements and licensing agreements, to protect Oxnimbi or any future product candidates and proprietary technology, including their respective components, formulations, therapies, methods used to manufacture them and methods of treatment.

Our commercial success depends in large part on our and our current and future licensors' ability to obtain, maintain, enforce and protect our patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and Oxnimbi and any future product candidates. We currently and in the future expect to generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to Oxnimbi and any future product candidates, proprietary technologies and uses of each that are material to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications or other intellectual property or proprietary rights from third parties. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting issued patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by proceedings instituted by third parties before various patent offices or in courts. We cannot offer any assurances that the breadth of our issued patents will be sufficient to stop a competitor from developing and commercializing a product, including a similar product that would be competitive with Oxnimbi or any future product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of Oxnimbi or any future product candidates. 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.

The patent prosecution process is expensive, time-consuming and complex. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them.

We may not be able to obtain or maintain patents and patent applications due to the subject matter claimed in such patent applications and patents being in the public domain. In some cases, the work of certain academic researchers has entered the public domain, which may preclude our ability to obtain patent protection for certain inventions relating to such work. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Consequently, we would not be able to prevent any third party from using any technology that is in the public domain to compete with Oxnimbi or any future product candidates. Moreover, we do not, with respect to our current in-licenses, and we may not, depending on the terms of any future in-licenses to which we may become a party, have the right to control the preparation, filing and

prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. There can be no assurance that our owned and in-licensed pending and future patent applications will result in patents being issued which protect our technology or Oxnimbi or any future product candidates, effectively prevent others from commercializing competitive technologies and product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, afford sufficient protection against competitors or other third parties with similar technology or products competitive with ours, including generic products that would be competitive with Oxnimbi or any future product candidates, or otherwise provide us with any competitive advantage, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Consequently, we do not know whether any of our technologies or Oxnimbi or any future product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing technologies and products, and the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. These uncertainties or limitations in our ability to properly protect the patent or other proprietary rights relating to Oxnimbi or any future product candidates could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority or entitlement disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. Our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art, as determined under applicable law. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to Oxnimbi or any future product candidates. For example, some patent applications in the United States may be maintained in secrecy until the patents are issued and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, under special circumstances, at issuance, or in some cases not at all. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor, were the first to invent or first to file an application for the technology.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition to the protection provided by our patent families, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. In addition, while we have undertaken reasonable efforts to ensure such agreements are enforceable and that employees and third parties comply with their obligations thereunder, these agreements may be found insufficient by a court of law or may be breached, or we may not enter into sufficient agreements with such individuals in the first instance, in either case potentially resulting in the unauthorized use or disclosure of our trade secrets, proprietary technology and information or other intellectual property, including to our competitors, which could cause us to lose any competitive advantage resulting from such intellectual property. Individuals not subject to invention assignment agreements may make adverse ownership claims to our current and future intellectual property. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could lawfully obtain our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Enforcing a claim that a third-party entity illegally obtained and is using any of

our trade secrets is expensive and time-consuming, and the outcome is unpredictable, and we may not be able to obtain adequate remedies for such breaches.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

The success of our business also depends in part on our ability to protect our unregistered intellectual property rights with respect to Oxnimbi or any future product candidates. We rely on certain unregistered intellectual property rights, including unpatented intellectual property, to protect and prevent others from duplicating our proprietary technology. Such means may afford only limited protection of our intellectual property and may not: (i) prevent our competitors from duplicating our technology; (ii) prevent our competitors from gaining access to our proprietary information and technology; or (iii) permit us to gain or maintain a competitive advantage.

Patent terms may be inadequate to protect our competitive position on Oxnimbi or any future product candidates for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of such product candidates, our business may be materially harmed.

Patents have a limited lifespan both in the United States and abroad. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest non-provisional application filing date in the applicable country. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering Oxnimbi or any future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. As a result, ours and our licensors' patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of Oxnimbi or any future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension (PTE) under the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a PTE of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. PTEs may also be available in certain foreign countries upon regulatory approval of Oxnimbi or any future product candidates. While, in the future, if such product candidates receive FDA approval, we expect to apply for PTEs on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. The length of extension, if granted, may be reduced if we are not diligent in testing and seeking approval of Oxnimbi or any future product candidates. Moreover, in any of the cases above, the length of the extension could be less than we request. If we are unable to obtain PTE or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing or generic products sooner. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

We in-license key intellectual property necessary for the development of Oxnimbi. If we fail to comply with our obligations in our current and any future intellectual property licenses with third parties, resulting in the termination of such licenses, we could lose rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and proprietary technology for the development of Oxnimbi, and we may enter into additional license agreements in the future. In particular, we in-license key patents and patent applications from BWH

related to Oxnimbi. The BWH License imposes diligence and milestone and royalty payment obligations on us, and also contains certain development requirements. If we fail to comply with our obligations, BWH may have the right to terminate the BWH License, in which event we will not be able to develop, manufacture or market any product using the intellectual property under any such terminated agreement and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Certain of our licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and Oxnimbi or any future product candidates in the future. In addition, the intellectual property rights licensed to us by BWH, at least in some respects, may be used by such licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against BWH or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

Oxnimbi or any future product candidates may require licenses to additional third-party intellectual property, technology and materials. These licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. In such events, we may be required to expend significant time and resources to redesign our technology, Oxnimbi or any future product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or Oxnimbi or any future product candidates. Even if we are able to obtain such additional licenses, they may be non-exclusive thereby giving our competitors and other third parties access to the same technology licensed to us.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize Oxnimbi or any future product candidates and technology could suffer. Although we have rights to review and provide input, BWH generally has the right to control the prosecution and maintenance of our in-licensed BWH patents and patent applications. Therefore, we cannot be certain that the prosecution and maintenance of these patent rights will be in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. In addition, subject to the terms of any future license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties in the future. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If we or our licensors fail to maintain such patents or patent applications, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize Oxnimbi or any future product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license or may license from third parties will also apply to patent rights we may own in the future.

Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide. In spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial and other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to transfer or assign the license;
- our right to sublicense patent and other rights to third parties under collaborative development relationships or otherwise;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of Oxnimbi or any future product candidates and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or Oxnimbi or any future product candidates. In addition, if any such disputes result in the termination of our intellectual property licenses, this could result in the loss of our ability to develop and commercialize Oxnimbi or we could lose other significant rights, experience significant delays in the development and commercialization of any future product candidates, or incur liability for damages, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with Oxnimbi or any future product candidates.

Some of our future agreements with certain of our third-party research partners may provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner. If we determine that rights to such improvements owned solely by a third-party research partner or other third party with whom we collaborate are necessary to commercialize Oxnimbi or any future product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing Oxnimbi or any future product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing Oxnimbi or any future product candidates or allow our competitors or others the chance to access technology that is important to our business.

Termination of our current or any future license agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of Oxnimbi or any future product candidates that rely on such agreements. Any of the foregoing could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize Oxnimbi or any future product candidates may be materially harmed.

In addition, a third party may in the future bring claims that our performance under our license agreements, including our sponsoring of clinical trials, interferes with such third party's rights under its agreement with one of our licensors. If any such claim were successful, it may adversely affect our rights and ability to advance Oxnimbi or any future product candidates as clinical candidates or subject us to liability for monetary damages, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described above and below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development program through acquisitions and in-licenses.

Presently, we have obtained rights to certain intellectual property rights through licenses from third parties, such as BWH, to develop, manufacture and commercialize Oxnimbi. The commercialization of Oxnimbi may require the use of additional intellectual property rights held by third parties. Oxnimbi or any future product candidates require specific formulations and manufacturing processes to work effectively and efficiently, and third parties may hold intellectual property rights to such technologies.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, important or more expedient to further our business operations. In addition, even if we are able to obtain such licenses, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Were that to happen, we may need to cease use of Oxnimbi or any future product candidates and technologies covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or violate those intellectual property rights, which may entail additional costs and development delays if we are able to develop such alternatives, or which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may

consider necessary or attractive in order to commercialize Oxnimbi or any future product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding any future product candidates that we may seek to acquire. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third-party intellectual property or maintain the existing intellectual property rights we have licensed, we may be required to expend significant time and resources to redesign Oxnimbi or any future product candidates, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis, and we may have to abandon development of Oxnimbi or any product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We currently depend, and will continue to depend, on our license agreements, including the BWH License. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If any of our licenses or material relationships or any in-licenses upon which our licenses are based are terminated or breached, we may:

- lose our rights to develop and market our products;
- lose patent protection for our products;
- experience significant delays in the development or commercialization of our products;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

These risks apply to any agreements that we may enter into in the future for Oxnimbi or for any future product candidates. If we experience any of the foregoing, it could have a material adverse effect on our business, financial condition, results or operations and prospects.

We cannot be certain that any of our owned or licensed pending patent applications or our future owned or licensed patent applications will result in issued patent claims covering Oxnimbi or any future product candidates.

Composition-of-matter patents on the active pharmaceutical ingredient (API) in prescription drug products provide a strong form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. Although we may file composition-of-matter patent applications in the future, we cannot be certain that our future owned or licensed patent applications will be issued as valid and enforceable patents or cover Oxnimbi or any future product candidates.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute. In addition, there are numerous publications and other prior art that may be relevant to our owned or in-licensed method-of-use patents and patent applications and may be used to challenge the validity of these owned or in-licensed patents and patent applications in litigation or other intellectual property-related proceedings. If these types of challenges are successful, our owned or in-licensed patents and patent

applications may be narrowed or found to be invalid, and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions, prospects and results of operations.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover Oxnimbi or any future product candidates or uses thereof in the United States or in other countries. Even if patents do successfully issue, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and third parties may challenge the validity, enforceability or scope of our owned and licensed patents in courts or patent offices in the United States and abroad, which may result in those patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own or license with respect to Oxnimbi or any future product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, Oxnimbi or any future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Competitors or other third parties may infringe the patents for which we have applied or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering Oxnimbi or any future product candidates, the defendant could counterclaim that the patent covering Oxnimbi or any future product candidate is invalid or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of amendment of our patents in such a way that they no longer cover Oxnimbi or any future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on Oxnimbi or any future product candidates that we own or may develop. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Even if we establish infringement of any of our intellectual property by a competitive product or competing activities of a third party, a court may decide not to grant an injunction against further infringing activity, thus allowing any such competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a “reasonable royalty” as determined by the court or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity or competition from a related product would have a material adverse impact on our business.

For certain of our in-licensed patent rights, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

In addition, we or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect

infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we or our licensors later sue such third party for patent infringement, the third party may have certain legal defenses available to it that otherwise would not be available but for the delay between when the infringement was first detected and when the suit was brought. These legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against that third party.

In addition, if the breadth or strength of protection provided by our future patents or the patents of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize Oxnimbi or any future product candidates. 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 stockholders perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights, including patents, of third parties. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violation of the intellectual property and proprietary rights of third parties. As Oxnimbi and any future product candidates progress toward commercialization, the possibility of an intellectual property infringement claim against us increases. We cannot provide any assurance that Oxnimbi or any future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to Oxnimbi or any future product candidates, including interference or derivation proceedings before the United States Patent and Trademark Office ("USPTO"), or oppositions and other proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that Oxnimbi or any future product candidates, manufacturing methods, formulations, administration methods or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights.

Numerous issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing Oxnimbi or any future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Oxnimbi or any future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, the claim scope that may issue from pending patent applications owned by third parties or which patents cover various types of drugs, products or their methods of use or manufacture. If a patent holder believes that Oxnimbi or any future product candidates infringe its patent, the patent holder may sue us even if we have received patent protection for our technology. We conducted a freedom-to-operate search for Oxnimbi in 2020. Additionally, 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 our research and other operations or necessary for the commercialization of Oxnimbi or any future product candidates in any jurisdiction. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that Oxnimbi or any future product candidates may infringe. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties, including our competitors, may allege they have patent rights encompassing Oxnimbi or any future product candidates, technologies or methods and that we are employing their proprietary technology without authorization.

Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. Even in such cases, if a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of Oxnimbi or any future product candidate that is the subject of the actual or threatened suit.

If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such U.S. patent. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is

especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

If any third-party patents are held by a court of competent jurisdiction to be valid and enforceable and to cover any of our technology or Oxnimbi or any future product candidates, including the manufacturing process of such product candidates, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If we were required to obtain such a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, ensure that any such license will be available on acceptable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively, or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing a product or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may be subject to claims that we and our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or trade secrets of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for 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 even if we are successful, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, harm to our reputation and other factors.

Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or stockholders perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing Oxnimbi or any future product candidates and platform discovery. Although it is our policy to require our employees, contractors and other third parties who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may

not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

In addition to seeking patents for Oxnimbi or any future product candidates, we rely, and expect to continue to rely in the future, on other proprietary rights, including the protection of our trade secrets, unpatented know-how, technology, and other confidential and proprietary information to maintain our competitive position. Trade secrets and know-how can be difficult to protect. If we rely on third parties to manufacture or commercialize Oxnimbi or any future product candidates, or if we collaborate with additional third parties for the development of such product candidates, we must at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We have taken steps to protect our proprietary technology trade secrets and unpatented know-how, in part by entering into confidentiality agreements and, if applicable, invention assignment agreements, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of our employees, consultants, or such third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Moreover, third parties may still obtain this information or may legally come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of skilled personnel from company to company or academic to industry scientific positions. If any of these events occur or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position could be harmed.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may independently develop similar or alternative technologies or duplicate Oxnimbi or any future product candidates or utilize similar technologies that are not covered by the claims of the patents we own or license;
- it is possible that others may circumvent our owned or in-licensed patents;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;

- it is possible that our owned or in-licensed patents or patent applications omit individual(s) who should be listed as inventor(s) or include individual(s) who should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- no patent protection may be available with regard to formulation or method of use;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover Oxnimbi or any future product candidates;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later be issued with claims covering our products or technology similar to ours;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may not exclusively license our patents and, therefore, may not have a competitive advantage if such patents are licensed to others;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the laws of other countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- countries other than the United States may, under certain circumstances, force us or our licensors to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not successfully commercialize Oxnimbi or any future product candidates, if approved, before our relevant patents expire;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that Oxnimbi or any future product candidates or technologies we develop may be covered by third parties' patents or other exclusive rights;
- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties and any issued patents that we own or license may be held invalid or unenforceable, including as a result of such legal challenges by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

We will not seek to protect our intellectual property rights in all geographical locations throughout the world and we may not be able to enforce our intellectual property rights even in the jurisdictions where we do seek and obtain protection.

Filing and prosecuting patent applications and defending patents covering Oxnimbi or any future product candidates and technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with Oxnimbi or any future product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market Oxnimbi or any future product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize Oxnimbi or any future product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Furthermore, various countries outside the United States, including certain countries in Europe, India, and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant

jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our future exclusive rights and limit our ability to contract with non-U.S. manufacturers.

The development of the patents we license from BWH was supported by U.S. government grants issued to BWH. Additionally, we may acquire or license in the future additional intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Patent and Trademark Act Amendments of 1980 (P.L. 96-517, as amended, the Bayh-Dole Act), the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercises its march-in rights in our currently licensed or future intellectual property rights that were or are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. or foreign patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect Oxnimbi or any future product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain, and changes in either the patent laws or interpretation of patent laws in the U.S. could increase the uncertainty and costs related to obtaining and enforcing patents. For example, the Leahy-Smith America Invents Act ("AIA"), which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other statutory requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This means that we must file our patent applications earlier in our development process rather than relying on proving priority of invention and it is now easier and less costly for third parties to attack our patents, all of which could harm our business, financial condition, results of operations, and prospects. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary

to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

We may become involved in opposition, interference, derivation, *inter partes* review or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed 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.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. 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. 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 in-licensed or that we may obtain in the future. Depending on decisions by Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. As of June 2023, our European Patent Office-registered patents are subject to the jurisdiction of the European and the European Unified Patent Court (the "UPC"). It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Complying with these laws and regulations could limit our ability to obtain new patents in the future, which may be important for our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We use and intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our current and future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with Oxnimbi or any future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The brand name Oxnimbi was conditionally approved by the FDA in May 2025, which was reconfirmed in June 2026, and is pending approval of the NDA in its totality. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names for the products we may develop, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names and such owners may file a lawsuit asking a court to force us to change our company or product names. If we 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. If we are unable to establish name recognition based on our trademarks and trade names for any of the foregoing reasons or otherwise, we may not be able to compete effectively and our business may be adversely affected.

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 sufficient 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 labeling 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 FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). Marketing exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications by other companies for a product with the same active moiety as a product we sell or may in the future sell. Specifically, in cases where NCE exclusivity has been granted, neither an ANDA nor a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, may 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.

We believe Oxnimbi (aroxybutynin, specifically) may be treated as an NCE under current FDA interpretations and, therefore, if approved, Oxnimbi should be afforded five years of data exclusivity; however, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product. The FDCA also provides three years of marketing exclusivity for a full NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant for an existing drug are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use if data exclusivity has expired.

There is no guarantee that Oxnimbi will qualify for marketing or data exclusivity under these provisions or that such exclusivity will alone be sufficient for our business. The applicable five-year and three-year exclusivity periods of NCE or data exclusivity under the FDCA will not delay the submission or approval of a full NDA.

With passage of the CREATES Act, we are exposed to possible litigation and damages by competitors. In addition, existing statutes, including the CREATES Act, and proposed legislation in Congress, if passed into law, could limit the patent exclusivity on our products or facilitate earlier entry of generic competition.

On December 20, 2019, the Creating and Restoring Equal Access to Equivalent Samples Act (the "CREATES Act") was signed into law. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMs for certain products, to deny generic and biosimilar product developers access to samples of brand brands. The CREATES Act established a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish necessary samples on "commercially reasonable, market-based terms." If we refuse any such request, we are exposed to possible litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of their ANDAs and 505(b)(2) applications. Such litigation would subject us to additional litigation costs, damages and reputational harm, which could lead to lower revenues. Increased risk of generic competition

with Oxnimbi or any future product candidates, if approved, including as a result of the CREATES Act, could impact our ability to maximize product revenue.

In addition, members of Congress have proposed numerous legislative initiatives aimed at limiting the patent exclusivity on drug products or facilitating earlier entry into the market of generic versions of approved drugs. Examples of bills that have been proposed include two bills that, if passed, would limit the number of patents from a patent family that an owner can bring against an infringer; a bill that, if passed, would empower the Federal Trade Commission to investigate whether a manufacturer's actions and follow on products constitute an anti-competitive practice and to file antitrust lawsuits in such instances; and a bill that, if passed, would limit the availability of a 30-month stay on approval by the FDA to a single covered patent elected by the holder at the time of first filing. Such legislation, if passed into law, could adversely affect Oxnimbi or any future products, if approved, or result in earlier entry into the market of generic versions of our drugs.

Risks Related to Government Regulation

Oxnimbi or any future candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended.

Any regulatory approvals that we may receive for Oxnimbi or any future product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, including boxed warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve Oxnimbi or any future product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve Oxnimbi or any future product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for Oxnimbi or any future product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with GCP for any clinical trials that we conduct post-approval. Further, the FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for their approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on companies' communications regarding off-label use, and if we or any contract sales force members we recruit market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other domestic and foreign regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities, or if previously unknown problems with any approved product, manufacturer, or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings or expanded boxed warnings;
- issuance of additional "Dear Doctor Letters" or similar communications to healthcare professionals;
- imposition of a REMS, or comparable foreign risk management approaches, which may include distribution or use restrictions;
- requirements to conduct additional post-marketing clinical trials to assess the safety of the product;
- civil or criminal penalties;
- fines, FDA Form 483s, warning letters, untitled letters or holds on clinical trials;
- injunctions;

- product seizures or detentions;
- product recalls;
- suspension, modification or withdrawal of regulatory approvals; and
- refusal by the FDA or other domestic or foreign regulatory authorities to approve pending applications for marketing approval of new products or supplements to approved applications.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Oxnimbi or any future product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay approval of Oxnimbi or any future product candidates we develop. 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 abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or CMOs are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of any approved products, which would adversely affect our business and results of operations.

Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay regulatory approval of Oxnimbi or any future product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell a product for which we obtain regulatory approval. Changes in laws, regulations, statutes or the interpretation of existing laws and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been, and continue to be, a significant number of legislative initiatives to contain healthcare costs. The United States has also sought to implement legislative initiatives at the state level, for instance, individual states are increasingly aggressive in passing legislation and implementing 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. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for Oxnimbi or any future product candidates or additional pricing pressures. In particular, any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business. For example, recent CMS proposals, including the Global Benchmark for Efficient Drug Pricing, Guarding U.S. Medicare Against Rising Drug Costs, the GENE rating cost Reductions for U.S. Medicaid model, could materially impact our revenue. CMS may develop additional payment and delivery models, including most-favored nation proposals, bundled payment models, or other drug pricing reforms, any of which could have a material adverse effect on our business.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and impose price controls may adversely affect the demand for Oxnimbi or any future product candidates, if we obtain regulatory approval; our ability to set a price that we believe is fair for our products; our ability to obtain coverage and reimbursement approval for a product; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

We expect that these existing laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare

or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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 fraud and abuse and other healthcare laws. 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 Oxnimbi or any future product candidates, if approved.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of a pharmaceutical manufacturer's business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws, regulations or case law. If any such actions are instituted against a pharmaceutical manufacturer, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, the curtailment or restructuring of our operations, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of operations. Further, defending against any such actions can be costly and time consuming, and may require significant financial and 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. If any of the physicians or other professionals or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Stringent and rapidly changing data privacy and security laws, regulations and other obligations related to the privacy and security of personal data could affect our business and failure or perceived failure to comply could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, increased compliance costs or other adverse consequences that could negatively affect our operating results and business.

We, and our third-party service providers, collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, share, and maintain personal data and other sensitive information, which may include proprietary and confidential business information, trade secrets, intellectual property, third-party information, and protected health information. Accordingly, we and those third-party service providers are, and may become, subject to federal, state, provincial, local, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security), guidance and industry standards, as well as external and internal privacy and security policies, contracts and obligations that apply to the processing of personal data by us or on our behalf. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, protection, transfer, security and processing of health-related and other personal information apply or could apply to our operations or the operations of our partners. For example, we may obtain health information from third parties (including research institutions and contracted third-parties from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). HIPAA and the respective implementing regulations impose certain obligations relating to the privacy, security, and transmission of individually identifiable health information. Depending on the facts and circumstances, we could be subject to significant penalties if we violate or cause our third-party service providers to violate HIPAA, such as substantial criminal or civil penalties if we knowingly receive protected health information from a HIPAA-covered entity (such as a healthcare provider, health plan, health care clearinghouses or research institution) that has not satisfied HIPAA's requirements for disclosure of such information to us or otherwise violates applicable requirements related to the protection of such information.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure, or misleading consumers regarding the protection, use or sharing of personal information, may constitute unfair or deceptive acts or practices in or affecting commerce in violation of the Federal Trade Commission Act of 1914. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to

improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC has also accused businesses of consumer deception based on overt or implied promises regarding personal information protection, including based on statements by company representatives. Any such misstatements, particularly regarding any aspects of our privacy or data security program, could lead to investigation and potential liability. In addition, concerns about cybersecurity have led the federal government to develop more stringent cybersecurity standards, which could impose operational costs and additional liability on our business.

At the state level, laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties and private litigation. For example, the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act, provides for individual privacy rights for California consumers (as the term "consumer" is defined in the law), including the right to opt out of certain disclosures of their information, and requires regulated businesses to comply with increased privacy and security obligations. The CCPA also provides a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach as well as expenses for data breach litigation. The CCPA also created a state regulatory agency to implement and enforce the law. Although there are exemptions for clinical trial data and HIPAA-regulated activities under the CCPA, compliance with the CCPA and other similar laws may increase our potential liability and require additional compliance costs, investment and potential business process changes, all of which may divert resources from other business activities.

As of January 2026, comprehensive laws similar to the CCPA have been adopted in 19 other states, adding complexity, variation in requirements, restrictions and potential legal risk, as well as requiring additional investment of resources in compliance programs. Although these laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including exemptions for clinical trials and HIPAA-regulated activities, they differ from each other in significant ways and may not have the same effect, thus, complicating compliance efforts. The existence of comprehensive privacy laws in different states also increases the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Furthermore, certain states have enacted laws that focus on narrower types of data and activities. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, protects consumer health data not subject to HIPAA. This law has a private right of action, which further increases our potential liability and the relevant compliance risk. Connecticut and Nevada have also adopted similar laws regulating consumer health data. Likewise, a small number of states, including Illinois and Texas, have enacted laws that specifically target the collection and use of biometric information. In addition, the federal government and a number of other states have proposed new privacy laws, some of which are similar to the laws discussed above, and some of which include requirements that exceed those imposed by such current laws. State laws are changing rapidly and there have been discussions in the U.S. Congress of new comprehensive federal data privacy laws to which we could become subject to, if enacted.

Regulators and legislators in the United States are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and the United States Government-Related Data by Countries of concern, as implemented by the U.S. Department of Justice's January 8, 2025 rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons" prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. This rule and related regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of this rule and related regulations may be punishable by criminal and civil sanctions and may result in exclusion from participation in federal and state programs.

Privacy laws can be interpreted in novel and unpredictable ways as well as subject to differing applications and interpretations which may be inconsistent or conflict among jurisdictions, leading to legal uncertainty. If we or our CMOs, CROs or other contractors or consultants fail to comply with U.S. and international data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), audits and inspections, additional reporting requirements, orders that limit our ability to use personal data (including an interruption or stoppage in our clinical trial efforts or commercialization of Oxnimbi or any future product candidates), private litigation (including privacy class action litigation, with risks of higher awards or settlements in the healthcare sector) or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, 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, financial condition, results of operations and prospects.

Foreign data, privacy and cybersecurity laws, including the EU's General Data Protection Regulation (the "EU GDPR"), and the United Kingdom ("UK") equivalent of the same (the "UK GDPR", together with the EU GDPR, the "GDPR"), Regulation (EU)

2023/2854 (the "EU Data Act") and Network Information Systems Directive 2 ("NISD 2") may also apply to our business activities.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area ("EEA"), or the UK. The GDPR applies to any company established in the EEA or UK as well as to those outside the EEA or UK if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or UK or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA member states and the UK governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and AE reporting. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requiring a legal basis or condition for the processing of personal data including sensitive data (such as health data), providing notice to the individuals to whom the personal data relates regarding data processing activities, limiting processing of such data to what is necessary for specified, explicit, and legitimate purposes, implementing safeguards to protect the privacy and security of personal data, requiring appointment of data protection officers in certain circumstances, increasing transparency obligations for data subjects, implementing processes to handle requests from individuals to exercise their data protection rights, maintaining records of our processing activities and to document data protection impact assessments where there is high risk processing, providing notification of data breaches in certain circumstances, and taking certain measures when engaging third-party processors or sub-processors. In particular, the processing of "special category personal data" (such as personal data related to health and genetic information), which could be relevant to our operations in the context of our conduct of clinical trials, imposes heightened compliance burdens under European data protection laws and is of interest to relevant regulators.

Companies that are subject to the GDPR face compliance obligations and risk, including regulatory enforcement and potential fines for noncompliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR remains a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In particular, EEA Member States have implemented national laws which may partially deviate from the EU GDPR and impose different and more restrictive obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA.

The GDPR also imposes strict rules on the transfer of personal data outside of the EEA and UK to countries that do not ensure an adequate level of protection, like the United States. We must, therefore, ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA or the UK, in compliance with European data protection laws. In some cases, we rely upon the European Commission approved standard contractual clauses to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the EU GDPR). The UK is not subject to the European Commission's standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the UK. Changes with respect to any of these mechanisms may lead to additional costs and increase our overall risk exposure. The EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (the "Framework"), which entered into force on July 10, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the U.S., the UK-U.S. Data Bridge, which entered into force on October 12, 2023 (the "UK Extension"). The Framework and the UK Extension thereto, as well as any other mechanisms to transfer personal data from the EEA or UK to the U.S. in compliance with law, are subject to legal challenge, and there is no assurance that we can satisfy or rely on these mechanisms to lawfully transfer personal data to the U.S.

The UK's data protection regime is independent from but aligned to the EU's data protection regime. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has issued an adequacy decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. Following the UK's adoption of the Data (Use and Access) Act 2025 on June 19, 2025, the European Commission adopted a decision on October 16, 2025 to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. While the EU GDPR and UK GDPR remain substantially similar for the time being, the respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future. Future changes to UK laws and regulations and their respective enforcement, and their interaction with EU laws and regulations and their respective enforcement, could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and require us to implement different compliance measures for the UK and the EEA.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA member states and the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. While we have taken steps to comply with the GDPR where applicable, including by

reviewing our security procedures and privacy policies, engaging data protection personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Furthermore, we may be subject to expanding cybersecurity legislation in the EU. The NISD 2, brings a large number of new industry sectors within scope of the cyber security regulation, including certain manufacturers of medical devices. NISD 2 imposes requirements to implement appropriate technical and organizational measures to manage risks to networks and information systems. There are also reporting requirements in the event there is an event having an actual effect on the security of the network and systems. We may need to undertake a compliance exercise to ensure we implement measures required under the EU Data Act and NISD 2, which may be an onerous, time-consuming and costly process.

In addition to the aforementioned data privacy and security laws, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. These constantly evolving laws and regulations and other contractual obligations can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions or notices (which could include civil or criminal penalties), fines, private litigation including class action-type, orders to cease or change our use of data, or adverse publicity and could negatively affect our operating results and business. Moreover, patients from whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, 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.

Disruptions at the FDA, SEC and other domestic and foreign government authorities, including changes in funding, leadership, staffing and policies, could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the United States market could be impacted. The ability of the FDA, SEC and other domestic and foreign government authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, changes in staffing and leadership, ability to hire and retain key leadership and other 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 authorities that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other domestic and foreign authorities may also slow the time necessary for new drugs to be reviewed and approved by necessary government authorities, which would adversely affect our business and timelines. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA 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 impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance the clinical development of Oxnimbi or any future product candidates along with our ability to receive timely review of any marketing application. Further, future shutdowns of other government authorities, such as the SEC, may also impact our business through review of our public filings and our ability to access the public markets.

The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business, including by posing security and other risks to our confidential or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may, and our third-party service providers may, use and integrate artificial intelligence into our business processes through both the development and implementation of artificial intelligence and the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The rapid

evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain such systems to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain artificial intelligence technology can give rise to intellectual property risks, including infringement of third-party intellectual property and compromises to our proprietary intellectual property, such as by disclosing or otherwise compromising our confidential or proprietary intellectual property or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of artificial intelligence tools. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

A growing number of federal, state and foreign legislators and regulators are adopting or considering adopting laws and regulations governing the use of artificial intelligence technology. These developments may increase the burden and costs in connection with the use, research, development and compliance in this area, and could lead to legal liability if we fail, or are perceived to fail, to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines. For example, Europe began implementing its EU Artificial Intelligence Act (the AI Act) on August 1, 2024, which, with some exceptions, is scheduled to come fully into effect on August 1, 2026. As currently enacted, the AI Act will impose significant obligations on providers and deployers of "high risk" artificial intelligence systems and includes fines of up to the greater of €35 million or 7% of worldwide annual turnover for violation.

In the United States, the artificial intelligence regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on artificial intelligence governance and regulation, including the deployment of artificial intelligence in healthcare settings. At the federal level, the Trump Administration has endorsed limiting state-level regulation of artificial intelligence technology, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." These efforts have contributed to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of artificial intelligence in regulated sectors. The FDA, for example, issued draft guidance on January 6, 2025, regarding the use of artificial intelligence in regulatory decision-making for drug and biological products that provides a risk-based credibility assessment framework for establishing and evaluating the credibility of an artificial intelligence model for a particular context of use. If we develop or use artificial intelligence technology governed by these laws or regulations, including as informed by regulatory guidance, we may need to adhere specific and potentially burdensome and costly ethical, accountability, and administrative requirements or standards, with the potential for significant enforcement or litigation in the event of any non-compliance or perceived non-compliance.

Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative artificial intelligence models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Changes in tax law may adversely affect us or our stockholders.

The rules dealing with federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, the One Big Beautiful Bill Act ("OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Under Section 174 of the Internal Revenue Code of 1986 (the "Code"), for instance, in taxable years beginning after December 31, 2021, expenses that are incurred for domestic research and development in the United States will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized under Section 174A of the Code. In addition, the OBBBA provides that, for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax

liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Risks Related to Our Business Operations, Employee Matters and Managing Growth and Other Risks Relating to Our Business

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

We have incurred substantial losses during our history, do not expect to become consistently profitable in the near future and may never achieve profitability. Our ability to use our federal and state net operating loss carryforwards ("NOLs") and other tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs, or other tax attributes. Under current federal tax law, unused U.S. federal NOLs arising in taxable years beginning before January 1, 2018, may be carried forward 20 taxable years to offset future taxable income, if any. U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the ability to use such federal NOLs to offset taxable income in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to current federal tax law.

As of December 31, 2025, we had $136.2 million of federal and $129.2 million of state NOLs. Of the amount of federal and state NOL carryforwards, $136.2 million can be carried forward indefinitely. The remaining federal and state NOL carryforwards begin to expire in 2039, unless previously utilized. Our NOLs are subject to review and possible adjustment by the federal and state tax authorities.

As of December 31, 2025 and 2024, we had federal research and development tax carryovers of $14.6 million and $10.8 million, respectively, and state research and development tax carryovers of $9.0 million and $6.5 million, respectively. The federal and state research credit carryforwards will begin to expire in 2039 and 2034, respectively, unless previously utilized. Our NOLs and research and development credits are subject to review and possible adjustment by the federal and state tax authorities.

In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by "5% stockholders" over a rolling three-year period, the corporation's ability to use its pre-change NOLs, research and development credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, research and development credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. The IPO, private placements and other transactions that have occurred since our inception may have triggered such an ownership change. We have not completed a study to assess whether any ownership changes have occurred since the date of our formation due to the significant complexity and cost associated with such a study. In addition, there may be future transactions that give rise to ownership changes. Changes to the U.S. tax rules in respect of the utilization of NOLs, research and development credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2026, we had 112 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational, quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources, the limited experience of our management team in managing a company with such anticipated growth and the complexity in managing a company that has scaled very quickly and anticipates continued growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of Oxnimbi or any future product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced, and we may not be able to

implement our business strategy, including the successful commercialization of Oxnimbi or any future product candidates, if approved.

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

Our ability to compete in the highly competitive pharmaceutical, biopharmaceutical and biotechnology industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We are highly dependent on the management, research and development, clinical, financial, and business development expertise of Kevin R. Lind, our Chief Executive Officer, Michael Kelly, our Chief Financial Officer, Dennis P. Molnar, our President and Chief Operating Officer, John Cronin, M.D., our Chief Medical Officer, Graham Goodrich, our Chief Commercial Officer, Barry Wohl, our Chief Business Officer, Steven Spector, J.D., our Chief Legal Officer and Head of Corporate Affairs, Luigi Taranto Montemurro, M.D., our Chief Scientific Officer and Beth Weinberg, RPh, our Chief Regulatory and Safety Officer. Each such officer may terminate their employment with us at any time.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of Oxnimbi toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. Furthermore, replacing executive officers and key employees 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, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical, biopharmaceutical and biotechnology companies for similar personnel, and consequently we may further be unable to maintain our positive company culture. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time and resources to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 ("SOX"), the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”), the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. SOX requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Further, pursuant to the Dodd-Frank Act, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We have a very small team with only 112 full-time employees as of September 30, 2026. We may need to hire additional financial reporting, internal controls and other finance personnel or consultants in order to develop and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. The increased costs will decrease our net income or increase our net loss and may require us to reduce expenditures in other areas of our business or increase the prices of our products, if approved. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply

with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our potential sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our internal computer systems, or those used by our CROs, contractors, consultants or other third parties upon which we rely, may fail or suffer cybersecurity incidents, compromises or breaches which could result in a material disruption to our operations and to the development of Oxnimbi or any future product candidates and other adverse consequences.

We rely on information technology systems that we or our third-party service providers operate to collect, handle, use, transmit, store and otherwise process information in our day-to-day operations. We may also share sensitive information with our partners or other third parties in conjunction with our business. Attempts to disrupt or gain unauthorized access to our and our third-party service providers' information technology systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by artificial intelligence. Despite the implementation of security measures designed to protect against cybersecurity incidents or data breaches, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers may be vulnerable to various threats including, but not limited to, damage from physical or electronic break-ins, computer viruses, malware, ransomware, social engineering attacks (including phishing attacks), personnel misconduct or error, supply chain attacks, natural disasters, terrorism, war, malfunctions, hardware, software, telecommunication or electrical failures, denial of service, malicious internet-based activity, online and offline fraud and other similar cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive or proprietary data, including personal information, and health-related information, and could subject us to significant liabilities, including regulatory and enforcement actions, as well as reputational damage. While we have implemented security measures designed to protect against such threats and cybersecurity incidents, there can be no assurance that these measures will be effective. We, and the third parties on whom we rely, have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure. We further expect to continue to experience threats and attempts to compromise the security of our information technology systems or otherwise cause a security incident. Moreover, these attacks and activity are being facilitated or enhanced by evolving technologies, including artificial intelligence, and we may not be able to anticipate, detect or remediate all security threats and vulnerabilities related to our information technology systems and infrastructure.

Cybersecurity incidents and data breaches can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of data, including data related to clinical trials, loss of income, significant extra expenses to restore data or systems, reputational loss, and the diversion of funds.

Additionally, theft or loss of our intellectual property, sensitive or personal data or proprietary business information could require substantial expenditures to remedy. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data and subsequently commercialize the product. Such theft or loss could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. We may expend significant resources, fundamentally change our business activities and practices, or modify or interrupt our operations, including our clinical trial activities, or information technology in an effort to protect against threats and to mitigate, detect, and remediate actual and potential vulnerabilities. Applicable data protection laws, contracts, policies, and other obligations related to data privacy, such as obligations

related to membership in industry organizations, may require us to implement specific security measures or adhere to certain security frameworks.

Our reliance on third-party service providers could also introduce new cybersecurity risks and vulnerabilities. Our ability to monitor the information security practices of our third-party service providers is limited, and these third parties may not have adequate information security measures in place. If we or our third-party service providers were to suffer a cybersecurity incident, compromise, or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, we may be subject to certain legal and contractual obligations. For example, we may have to notify consumers, partners, collaborators, government authorities, other stakeholders and the media. Moreover, we may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Any such disclosures may involve inconsistent requirements and are costly and could lead to adverse consequences. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. While we may be entitled to damages if these providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. In addition to experiencing a cybersecurity incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Our reliance on internet technology and the number of our employees, and those of our CROs, who continue to work remotely may create additional opportunities for cybercriminals to exploit vulnerabilities, as this has caused an increased usage of computers operated on home networks, while in transit, or in public locations. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience cybersecurity incidents, compromises, or breaches that may remain undetected for an extended period.

Furthermore, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are enforceable or sufficient to protect us from liabilities, damages, or claims related to information security, security incidents and data breaches. We cannot be sure that any insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Any of the aforementioned threats or system failures could cause a security incident or data breach, which, in turn, could result in harm to our business such as unauthorized access to, damage to, disablement or encryption of, use or misuse of, disclosure of, modification of, destruction of, or loss of our data. If a cyber incident or data breach were to occur, we may incur liability and suffer reputational harm. Further, a cybersecurity incident or data breach may result in a delay of the development and commercialization of Oxnimbi or any future product candidates. Additionally, regulators could impose penalties and monetary fines against us for similar concerns, or we could incur other liability in connection with or resulting from litigation or governmental investigations and enforcement actions. The discontinuance of relationships with third parties, or the failure to meet the expectations of such third parties, or litigation, regulatory investigation or enforcement, could result in material harm to our operations, financial performance or reputation and affect our ability to grow and operate our business. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could materially and adversely affect our business.

We are 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 stockholder confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of SOX ("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 ending December 31, 2027. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Prior to our IPO, we had not been required to test our internal controls within a specified time period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in

maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business.

We may discover new weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. We are currently remediating a material weakness in our internal controls over financial reporting related to fiscal years 2025 and 2024, which relates to an ineffective control environment, including a lack of formal documented risk assessment and monitoring controls and insufficient information technology controls, including access and change management controls over financial reporting. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, or if we determine we have a new material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, our stockholders could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We have previously identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate a material weakness or if we otherwise fail to establish and maintain effective control over financial reporting, it has in the past and may in the future adversely affect our ability to accurately and timely report our financial results, which may adversely affect stockholder confidence and business operations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For example, we have filed an amendment to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 to restate our previously issued unaudited condensed consolidated financial statements as of and for the three and six months ended June 30, 2026 and related disclosures due to the identification of an error in the classification of our $85.4 million gain on the disposition of our equity method investment in SASS (the "Restatement"). This gain was incorrectly classified within other income in continuing operations, rather than within discontinued operations. Management is assessing the effect of the Restatement on our internal control over financial reporting and our disclosure controls and procedures.

In connection with the audit of our consolidated financial statements as of and for the years ended December 31, 2025 and 2024, we identified a material weakness in our internal control over financial reporting that we are currently working to remediate, which relates to an ineffective control environment, including a lack of formal documented risk assessment and monitoring controls, insufficient information technology controls, including access and change management controls over financial reporting, and a lack of sufficient levels of accounting personnel to maintain proper control activities over classification, valuation and disclosure over non-routine or complex transactions.

We started our remediation efforts during the year ended December 31, 2024 and efforts have continued into 2026. In 2025, we implemented a new enterprise resource planning system, and designed a risk assessment process. Also, in 2025 and into 2026, we've continued to hire additional resources to support accounting and finance. In an effort to continue to remediate this material weakness, we intend to design and implement processes and internal controls over our information and technology, finalize and document our risk assessment, and further develop and document our accounting policies and financial reporting procedures, including documenting our senior management and audit committee oversight.

We are focused on designing and implementing effective internal control measures to improve our evaluation of disclosure controls and procedures, including internal control over our information technology and related financial reporting, and remediating the material weakness.

However, we cannot provide assurance that the measures we are taking to remediate the material weakness will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements in the future. In such a case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of the Nasdaq, stockholders may lose confidence in our financial reporting and our stock price may decline as a result. Moreover, investors may view our historical financial information as less reliable as a result of the Restatement and the identification of a

material weakness in our internal control over financial reporting. This perception could impact investor confidence, adversely affect the market price of our securities, impair our ability to access capital markets and result in greater difficulty in achieving strategic or financial objectives.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile and our stockholders could incur substantial losses.

Our stock price is likely to be volatile. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the Quarterly Report titled “Risk Factors” and the following:

- our ability to advance Oxnimbi toward regulatory approval and our ability to successfully commercialize Oxnimbi, if approved;
- our ability to educate the OSA medical community, patients and payors on the benefits of Oxnimbi, if approved;
- the success of competitive products and therapies;
- results of our nonclinical studies and clinical trials of Oxnimbi or any future product candidates, or those of our competitors or potential collaborative partners;
- actions taken by regulatory authorities with respect to Oxnimbi or any future product candidates, clinical trials, manufacturing process or sales and marketing terms;
- developments concerning any current or future collaborations, including, but not limited to, those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- manufacturing, supply or distribution delays or shortages;
- the success of our efforts to acquire or in-license additional technologies or any future product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, financing efforts or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for Oxnimbi or any future product candidates;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to Oxnimbi or any future product candidates;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by stockholders to be comparable to us;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- macroeconomic conditions, including volatility in the credit and financial markets, inflationary pressures and geopolitical unrest on the global economy; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Our operating results may fluctuate significantly or may fall below the expectations of our stockholders or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- if Oxnimbi or any future product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- variations in the level of expense related to the ongoing development of Oxnimbi or any future product candidates or development programs;
- coverage and reimbursement policies with respect to Oxnimbi or any future product candidates, if approved, and potential future drugs that compete with our products;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments, including milestone or royalty payments, we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- regulatory developments affecting Oxnimbi or any future product candidates or those of our competitors;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- future accounting pronouncements or changes in our accounting policies;
- additions and departures of key personnel; and
- changes in general market and economic conditions.

If our quarterly and annual operating results fall below the expectations of our stockholders or securities analysts, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. Furthermore, any quarterly fluctuations in our operating results may, in turn,

cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts cease coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We will not receive any meaningful amount of additional funds upon the exercise of the Warrants.

Each Warrant will be exercisable until April 2, 2036 by means of payment of the nominal cash purchase price upon exercise or by means of a "cashless exercise" according to a formula set forth in the Warrant. Accordingly, we will not receive any meaningful additional funds upon the exercise of the Warrants.

An active trading market for our common stock may not continue to develop or be sustained.

Our common stock began trading on Nasdaq on July 31, 2026. Prior to July 31, 2026, there was no public market for our common stock, and we cannot provide assurance that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for our shares, or at all.

We have broad discretion in the use of our cash, cash equivalents and restricted cash, and we may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and restricted cash and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock or in ways with which our stockholders may not agree. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates and any other product candidates we may develop.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates own a significant portion of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. Additionally, one of our principal stockholders, Alpha Wave Ventures II, LP, has an employee who sits on our board of directors. The interests of these stockholders may not be the same as or may even conflict with the interests of other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to stockholders perception that conflicts of interest may exist or arise.

Future sales of our common stock in the public market or rights to purchase common stock and issuances of common stock upon the exercise of outstanding warrants or warrants issued in the future could cause our common stock price to fall and would result in additional dilution of the percentage ownership of our stockholders.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

All shares of common stock sold in the IPO are freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining 27,999,640 shares, or 67%

of our outstanding shares of common stock as of September 30, 2026, is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with the IPO. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of the IPO Prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements, or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.

In addition, as of April 2, 2026, we had outstanding Warrants exercisable for 100,163 shares of our common stock. The Warrants may be exercised at any time after the date of issuance through either a nominal cash payment or a cashless exercise, at the holder's election, until April 2, 2036. Additionally, pursuant to the Credit Agreement, we are obligated to issue warrants to Lenders as a condition to the Lenders' obligation to advance the Tranche B Term Loan and the Tranche C Term Loan to us (the "Tranche Warrants"). If some or all of the Warrants are exercised or the Tranche Warrants are issued and subsequently exercised, our stockholders could experience additional dilution and such exercise may cause the market price of our stock to decline.

Additionally, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders sole source of gain for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise may dilute all other stockholders, restrict our operations or require us to relinquish rights to our technologies or Oxnimbi or any future product candidates.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. We have and may in the future enter into debt agreements requiring us to issue equity securities in connection with such debt agreements. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, Oxnimbi or any future product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market Oxnimbi or any future product candidates that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to stockholders.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden

parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements. We cannot predict if stockholders will find our common stock less attractive because we may rely on these exemptions. If some stockholders find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our ninth amended and restated certificate of incorporation and our second amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management without the consent of our board of directors or significantly reduce the value of our shares to a potential acquiror. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chair of our board of directors, our chief executive officer or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each;
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine; and
- requirement for the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our ninth amended and restated certificate of incorporation or second amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended ("DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of

15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

Our second amended and restated bylaws provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums 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 second amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, other employees or stockholders to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our ninth amended and restated certificate of incorporation, or our second amended and restated bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our ninth amended and restated certificate of incorporation or our second amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder);
- any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our second amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

Such exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our current or former directors, officers, other employees or stockholders, which may discourage such lawsuits against us and our current and former directors, officers, other employees and stockholders even if an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. These exclusive forum provisions may also impose additional litigation costs on stockholders in pursuing any such claims.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our second amended and restated bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

General Risk Factors

We may incur significant costs from class action litigation due to our expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts, the development efforts and commercial success of future partners or competitors, the addition or departure of our key personnel, variations in our operating results and changes in market valuations of pharmaceutical, biopharmaceutical and biotechnology companies. This risk is especially relevant to us because pharmaceutical, biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Changes to the United States presidential administration and policy changes that have or may result therefrom could also adversely affect financial markets and general economic conditions under which we operate. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.

We and any of our third-party manufacturers or suppliers and current or potential future collaborators may use biological materials, potent chemical agents, and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we nor our third-party manufacturers and suppliers can eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our or our manufacturers' or suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous, or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations, and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international 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 Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act of 1961, the USA PATRIOT Act of 2001, 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 collaborators 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 engage third parties to sell our products outside the United States, to conduct clinical trials, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We 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 collaborators, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective. 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.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

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

(a) Use of Proceeds from our Initial Public Offering

On July 30, 2026, the SEC declared effective our Registration Statement filed with the SEC in connection with our IPO. Pursuant to the Registration Statement, we registered the offer and sale of 13,800,000 shares of our common stock, including 1,800,000 shares of common stock subject to the underwriters' option to purchase additional shares of common stock, with a maximum aggregate offering price of $220.8 million. BofA Securities, Inc., Evercore Group L.L.C. and Cantor Fitzgerald & Co. acted as representatives of the underwriters for the IPO. We received net proceeds of approximately $198.9 million from the sale of 13,800,000 shares of common stock at a price of $16.00 per share, which included 1,800,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities or our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in the IPO Prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the quarter ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

Exhibit Number	Description
3.1	Ninth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-43422) filed with the Securities and Exchange Commission on August 3, 2026).
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-43422) filed with the Securities and Exchange Commission on August 3, 2026).
10.1·	Apnimed, Inc. 2026 Inducement Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-298803) filed with the Securities and Exchange Commission on September 8, 2026).
10.2·	Form of Non-Qualified Stock Option Agreement under the Apnimed, Inc. 2026 Inducement Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-298803) filed with the Securities and Exchange Commission on September 8, 2026).
10.3·	Form of Restricted Stock Unit Award Agreement under the Apnimed, Inc. 2026 Inducement Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-298803) filed with the Securities and Exchange Commission on September 8, 2026).
31.1+	Certification of Principal Executive Officer 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.
31.2+	Certification of Principal Financial Officer 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.
32.1+†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH+	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104+	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Filed herewith.

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report are deemed "furnished" and not "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

· Indicates management contract or compensatory plan.

SIGNATURES

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

Apnimed, Inc.

Date: November 16, 2026

By: /s/ Kevin R. Lind
Kevin R. Lind
Chief Executive Officer

Date: November 16, 2026

By: /s/ Michael Kelly
Michael Kelly
Chief Financial Officer

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, Kevin R. Lind, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2026 of Apnimed, 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 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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 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 16, 2026

By: /s/ Kevin R. Lind

Kevin R. Lind
Chief Executive Officer 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, Michael Kelly, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2026 of Apnimed, 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 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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 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 16, 2026 By: /s/ Michael Kelly

Michael Kelly
Chief Financial Officer
(Principal Financial Officer 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 Apnimed, Inc. (the "Company") for the period ended September 30, 2026 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:

(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 16, 2026

By: /s/ Kevin R. Lind
Kevin R. Lind
Chief Executive Officer 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 Apnimed, Inc. (the "Company") for the period ended September 30, 2026 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:

(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 16, 2026 By: /s/ Michael Kelly

Michael Kelly
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)