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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 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: 001-38890

Quince Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**90-1024039**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
611 Gateway Boulevard, Suite 273 South San Francisco, California	**94080**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (415) 910-5717

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 $0.001 per share	QNCX	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of August 7, 2026, the registrant had 1,017,063 shares of common stock, $0.001 par value per share, outstanding.

EXPLANATORY NOTE

On April 10, 2026, the Company effected a reverse stock split of all shares of its issued and outstanding common stock at a ratio of 1-for-10. On June 29, 2026, the Company effected a reverse stock split of all shares of its issued and outstanding common stock at a ratio of 1-for-20. The Company accounted for these reverse stock splits on a retrospective basis pursuant to Accounting Standards Codification ("ASC") 260, Earnings Per Share. All issued and outstanding shares of common stock and share-based awards' exercise prices and per share data in this report and the unaudited condensed consolidated financial statements have been adjusted, on a retrospective basis, to reflect the reverse stock splits for all periods presented. The number of authorized shares and par value of the common stock were not adjusted because of the reverse stock splits.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "expect," "objective," "plan," "potential," "seek," "grow," "target," "if," and similar expressions intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other filings with the Securities and Exchange Commission (the "SEC"). It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report on Form 10-Q may not occur, and actual results may differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to successfully integrate the operations of the Company and Orphai (as defined below) and to realize the anticipated benefits of our acquisition of Orphai, including the advancement of the combined pipeline and the need to hire additional employees and our ability to attract and retain our personnel, including key personnel;
- the ability of our preclinical studies and clinical trials to demonstrate acceptable safety and efficacy of our product candidates;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials;
- the timing, progress and results of preclinical studies and clinical trials for our current and future product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including Investigational New Drug ("IND") submissions for our product candidates;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our financial performance;
- the accuracy of our estimates regarding expenses, liquidity requirements, and needs for additional financing;
- our expectations related to the use of our available cash;

- our ability to obtain funding for our operations;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- potential claims relating to our intellectual property; and
- our ability to maintain compliance with Nasdaq listing requirements.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we do not intend to update any of these forward-looking statements after the date of this Quarterly Report on Form 10-Q or to conform these statements to actual results or revised expectations.

You should read this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

This Quarterly Report on Form 10-Q contains estimates, projections and other information concerning our industry, our business and the markets for our drug candidates. We obtained the industry, market and similar data set forth in this report from our own internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified these data. Further, while we believe our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

Unless the context requires otherwise, the terms (i) “we,” “us,” “our,” “Quince,” the “Company” and other similar terms refer to the business and operations of Quince Therapeutics, Inc. and its consolidated subsidiaries for periods prior to the Acquisition (as defined below) and to Orphai Holdings Therapeutics, Inc. and its consolidated subsidiaries, including Orphai Therapeutics, LLC, for periods after the Acquisition; (ii) “Orphai HoldCo” refers to Orphai Holdings Therapeutics, Inc., (iii) “Orphai Subsidiary” refers to Orphai Therapeutics, LLC, a wholly owned subsidiary of Orphai HoldCo, (iv) “Orphai” or “Orphai Therapeutics” refer collectively to Orphai HoldCo and Orphai Subsidiary and (v) “Orphai Acquisition” refers to the acquisition by the Company of Orphai Therapeutics pursuant to that certain Agreement and Plan of Merger, dated May 17, 2026 (the "Merger Agreement"), by and among the Company, Phoenix Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Phoenix Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, Orphai Subsidiary, and Orphai HoldCo.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share amounts)

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 115,981	$ 5,809
Short-term investments	—	11,943
Prepaid expenses and other current assets	7,430	5,144
Total current assets	123,411	22,896
Property and equipment, net	506	595
Operating lease right-of-use assets	—	453
Intangible assets	—	67,819
Other assets	78	1,760
Total assets	$ 123,995	$ 93,523
LIABILITIES, MEZZANINE EQUITY, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,636	$ 2,223
Accrued expenses and other current liabilities	3,864	10,608
Current portion of debt	—	18,026
Short-term contingent consideration	—	12,369
Total current liabilities	8,500	43,226
Long-term operating lease liabilities	—	330
Long-term contingent consideration	—	51,961
Warrant liabilities	6,292	32,150
Other long-term liabilities	716	1,570
Total liabilities	15,508	129,237
Mezzanine equity:		
Series C Preferred Stock, $0.001 par value, 294,370 shares and no shares designated as of June 30, 2026 and December 31, 2025, respectively; 211,301.868 and no shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	143,811	—
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.001 par value, 250,000,000 shares authorized, 1,017,063 and 278,627 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively[(1)]	1	—
Additional paid in capital[(1)]	460,447	418,987
Accumulated other comprehensive income	4,255	5,750
Accumulated deficit	(500,027)	(460,451)
Total stockholders' equity (deficit)	(35,324)	(35,714)
Total liabilities, mezzanine equity, and stockholders' equity (deficit)	$ 123,995	$ 93,523

[(1)] Adjusted prior period common stock and additional paid-in-capital to reflect the 1-for-10 reverse stock split effected on April 10, 2026 and the 1-for-20 reverse stock split effected on June 29, 2026.

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

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 5,461	$ 6,553	$ 12,306	$ 14,698
Acquired in-process research and development	59,000	—	59,000	—
General and administrative	16,626	3,342	20,893	8,131
Gain on Orphai Acquisition	(1,305)	—	(1,305)	—
Intangible asset impairment charge	—	—	67,808	—
Fair value adjustment for contingent consideration	—	532	(64,330)	2,456
Total operating expenses	79,782	10,427	94,372	25,285
Loss from operations	(79,782)	(10,427)	(94,372)	(25,285)
Fair value adjustment for debt	—	(501)	12,168	(945)
Fair value adjustment for warrants	4,507	(4,464)	35,623	(4,464)
Warrant issuance costs	(874)	(872)	(874)	(872)
Interest income	584	311	744	717
Other (expense) income, net	152	(29)	1,871	(116)
Net loss before income tax expense	(75,413)	(15,982)	(44,840)	(30,965)
Income tax benefit (expense)	(75)	(67)	5,264	(114)
Net loss	(75,488)	(16,049)	(39,576)	(31,079)
Other comprehensive loss:				
Foreign currency translation adjustments	(355)	4,216	(1,490)	6,261
Unrealized loss on available-for-sale securities	—	(17)	(5)	(70)
Total comprehensive loss	$ (75,843)	$ (11,850)	$ (41,071)	$ (24,888)
Net loss per share – basic and diluted [(1)]	$ (12.31)	$ (68.75)	$ (12.01)	$ (137.17)
Weighted average shares of common stock and in-substance common stock outstanding – basic and diluted [(1)]	6,132,845	233,431	3,295,727	226,571

[(1)] Adjusted prior period net loss per share and weighted average of common shares outstanding to reflect the 1-for-10 reverse stock split effected on April 10, 2026 and the 1-for-20 reverse stock split effected on June 29, 2026.

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

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF SERIES C PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands, except share and per share amounts)

	For the three months ended June 30, 2026 and 2025							
	Series C Preferred Stock		Common Stock[1]		Additional Paid in Capital[1]	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of March 31, 2026	—	$ —	689,541	$ 1	$ 435,600	$ 4,610	$ (424,539)	$ 15,672
Issuance of common stock in connection with the ATM offerings, net	—	—	125,510	—	5,351	—	—	5,351
Issuance of common stock in connection with the Orphai Acquisition	—	—	162,971	—	3,242	—	—	3,242
Issuance of Series C Preferred Stock in connection with the Orphai Acquisition	67,101.235	48,146	—	—	—	—	—	—
Issuance of Series C Preferred Stock in connection with private placement offering, net of issuance costs	144,200.633	95,665	—	—	—	—	—	—
Fractional shares round up due to June 2026 Reverse Stock Split	—	—	39,041	—	—	—	—	—
Fair value of replacement awards issued as consideration in Orphai Acquisition	—	—	—	—	4,161	—	—	4,161
Stock based compensation	—	—	—	—	12,093	—	—	12,093
Foreign currency translation adjustment	—	—	—	—	—	(355)	—	(355)
Net loss	—	—	—	—	—	—	(75,488)	(75,488)
Balance as of June 30, 2026	211,301.868	143,81 $ 1	1,017,063	$ 1	$ 460,447	$ 4,255	$ (500,027)	$ (35,324)
Balance as of March 31, 2025	—	$ —	220,446	$ —	$ 408,126	$ 1,957	$ (391,502)	$ 18,581
Issuance of common stock and warrants in private placement offering, net	—	—	33,360	—	746	—	—	746
Issuance of common stock in connection with the ATM offerings, net	—	—	13,833	—	2,890	—	—	2,890
Issuance of common stock on exercise of stock options and vesting of restricted stock units	—	—	483	—	96	—	—	96
Stock based compensation	—	—	—	—	1,273	—	—	1,273
Foreign currency translation adjustment	—	—	—	—	—	4,216	—	4,216
Unrealized loss on available for sale investments	—	—	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	—	—	(16,049)	(16,049)
Balance as of June 30, 2025	—	$ —	268,122	$ —	$ 413,131	$ 6,156	$ (407,551)	$ 11,736

[1] Adjusted prior period common stock and additional paid-in-capital to reflect the 1-for-10 reverse stock split effected on April 10, 2026 and the 1-for-20 reverse stock split effected on June 29, 2026.

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

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF SERIES C PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands, except share and per share amounts)

For the six months ended June 30, 2026 and 2025

	Series C Preferred Stock		Common Stock[1]		Additional Paid in Capital[1]	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	—	$ —	278,627	$ —	$ 418,987	$ 5,750	$ (460,451)	$ (35,714)
Issuance of common stock in connection with the ATM offerings, net	—	—	526,435	1	20,337	—	—	20,338
Issuance of common stock on exercise of pre-funded warrants, net	—	—	9,989	—	341	—	—	341
Issuance of common stock in connection with the Orphai Acquisition	—	—	162,971	—	3,242	—	—	3,242
Issuance of Series C Preferred Stock in connection with the Orphai Acquisition	67,101.235	48,146	—	—	—	—	—	—
Issuance of Series C Preferred Stock in connection with private placement offering, net of issuance costs	144,200.633	95,665	—	—	—	—	—	—
Fractional shares round up due to June 2026 Reverse Stock Split	—	—	39,041	—	—	—	—	—
Fair value of replacement awards issued as consideration in Orphai Acquisition	—	—	—	—	4,161			4,161
Stock based compensation	—	—	—	—	13,379	—	—	13,379
Foreign currency translation adjustment	—	—	—	—	—	(1,490)	—	(1,490)
Unrealized loss on available for sale investments	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(39,576)	(39,576)
Balance as of June 30, 2026	211,301.868	143,811	1,017,063	$ 1	$ 460,447	$ 4,255	$ (500,027)	$ (35,324)
Balance as of December 31, 2024	—	$ —	220,009	$ —	$ 406,653	$ (35)	$ (376,472)	$ 30,146
Issuance of common stock and warrants in private placement offering, net	—	—	33,360	—	746	—	—	746
Issuance of common stock in connection with the ATM offerings, net	—	—	13,833	—	2,890	—	—	2,890
Issuance of common stock on exercise of stock options and vesting of restricted stock units	—	—	920	—	183	—	—	183
Stock based compensation	—	—	—	—	2,659	—	—	2,659
Foreign currency translation adjustment	—	—	—	—	—	6,261	—	6,261
Unrealized loss on available for sale investments	—	—	—	—	—	(70)	—	(70)
Net loss	—	—	—	—	—	—	(31,079)	(31,079)
Balance as of June 30, 2025	—	$ —	268,122	$ —	$ 413,131	$ 6,156	$ (407,551)	$ 11,736

[1] Adjusted prior period common stock and additional paid-in-capital to reflect the 1-for-10 reverse stock split effected on April 10, 2026 and the 1-for-20 reverse stock split effected on June 29, 2026.

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

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the Six Months Ended June 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (39,576)	$ (31,079)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	13,379	2,659
Depreciation and amortization	77	67
Change in the fair value of contingent consideration liabilities	(64,330)	2,456
Change in fair value of debt, net	(12,197)	828
Change in fair value of warrants	(35,623)	4,464
Gain on settlement of accounts payable	(3,720)	—
Intangible asset impairment charge	67,808	—
Acquired in-process research and development from the Orphai Acquistion	59,000	—
Gain on Orphai Acquisition	(1,305)	—
Amortization of discount on available-for-sale investments	(62)	(590)
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other current assets	(3,277)	588
Right of use assets, operating leases and operating lease liabilities	451	53
Other assets	1,774	(121)
Accounts payable	6,171	(1,417)
Accrued expenses and other current liabilities	(15,097)	1,103
Other liabilities	13	(27)
Net cash used in operating activities	(26,514)	(21,016)
Cash flow from investing activities:		
Purchase of investments	—	(13,789)
Proceeds from maturities of investments	12,000	31,000
Purchase of property and equipment	—	(274)
Net cash assumed in the Orphai Acquisition	8,001	—
Net cash provided by investing activities	20,001	16,937
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	—	183
Proceeds from issuance of common stock, common warrants, and pre-funded warrants pursuant to June 2025 private placement offering, net of issuance costs	—	11,426
Proceeds from issuance of Series C Preferred Stock and Financing Warrants pursuant to May 2026 private placement offering, net of issuance costs	103,639	—
Issuance of common stock in connection with the ATM offerings, net of issuance costs	20,338	2,890
Repayment of debt	(5,545)	—
Cash settlement of common warrants	(56)	—
Net cash provided by financing activities	118,376	14,499
Effect of exchange rate changes on cash	(1,691)	194
Net increase in cash and cash equivalents	110,172	10,614
Cash and cash equivalents at beginning of period	5,809	6,212
Cash and cash equivalents at end of period	$ 115,981	$ 16,826
Supplemental disclosures of cash flow and non-cash information:		
Cash paid for interest	$ 29	$ 117
Offering costs in accounts payable and accrued expenses	$ —	$ 193
Noncash exercise of pre-funded warrants	$ 341	$ —
Common stock and Series C Preferred Stock issued in connection with Orphai Acquisition	$ 51,388	$ —
Fair value of replacement awards issued as consideration in the Orphai Acquisition	$ 4,161	$ —
Net liabilities assumed in connection with Orpahi Acquisition	$ 9,283	$ —

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

QUINCE THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

Note 1. Organization

Description of Business

Quince Therapeutics, Inc. ("Quince" or the "Company") is a clinical-stage biopharmaceutical company developing a novel disease modifying therapeutic to address the significant unmet medical need associated with pulmonary disorders with few, if any, treatment options available.

Prior to the Orphai Acquisition (defined below), the Company was focused on developing its proprietary Autologous Intracellular Drug Encapsulation (“AIDE”) technology for the treatment of Ataxia-Telangiectasia (“A-T”) through its encapsulated dexamethasone sodium phosphate encapsulated in patient's own red blood cells (“eDSP”) product candidate. In January 2026, the Company completed its pivotal Phase 3 NEAT clinical trial of eDSP for the treatment of A-T. The primary endpoints of the NEAT trial did not reach statistical significance. Based on the results of the NEAT trial, the Company determined that it would no longer continue development of eDSP in this or other therapeutic indications, and is currently considering next steps for the eDSP program and other assets.

Orphai Acquisition

On May 18, 2026, the Company completed the Acquisition of Orphai (the "Orphai Acquisition"), in accordance with the terms of the Agreement and Plan of Merger, dated May 17, 2026 (the “Merger Agreement”). In connection with the Orphai Acquisition, the Company acquired Orphai’s lead asset, LAM-001, a proprietary investigational inhaled dry powder formulation of rapamycin whose differentiated characteristics may permit treatment of conditions associated with dysfunctional mammalian target of rapamycin (“mTOR”) activity that cannot be adequately treated using a systemically delivered formulation, including oral solution or tablets. Following the Orphai Acquisition, the Company’s lead product candidate is LAM-001. See Note 3 for further details.

Liquidity and Capital Resources

The Company has incurred losses and negative cash flows from operations since inception and expects to continue to generate operating losses for the foreseeable future. As of June 30, 2026, the Company had an accumulated deficit of $500.0 million. Since inception through June 30, 2026, the Company has funded operations primarily with the net proceeds from the sale of its securities, from the net proceeds from the Company’s initial public offering (the “IPO”) and from the net proceeds of private investments in public equity transactions (collectively known as “PIPE Financings”), including the concurrent private placement in May 2026 described below. As of June 30, 2026, the Company had cash and cash equivalents of $116.0 million.

The Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these unaudited condensed consolidated financial statements are issued.

Concurrent with the Orphai Acquisition, in May 2026, the Company completed a private placement financing of the Company’s Series C Non-Voting Convertible Preferred Stock (the “Series C Preferred Stock”) and warrants to purchase shares of Series C Preferred Stock, providing $115.0 million in gross upfront proceeds, with the potential to receive up to an additional $72.0 million in gross proceeds upon the exercise of the warrants (with an additional up to $11.0 million in gross proceeds available upon the exercise of warrants issued to former Orphai stockholders). The Series C Preferred Stock is subject to automatic conversion into common stock upon the third business day following the Company’s receipt of stockholder approval in accordance with Nasdaq Listing Rules, subject to certain beneficial ownership limitations. The Certificate of Designation of Preferences, Rights and Limitations of the Series C Non-Voting Convertible Preferred Stock (the “Certificate of Designation”) provides that, at any time following the earlier of (i) stockholder approval or (ii) six months after the initial issuance of the Series C Preferred Stock, if the Company fails to timely deliver shares of common stock to a converting holder in accordance with the terms of the Certificate of Designation, such holder may require

the Company to pay cash in an amount equal to the fair value of the undelivered shares. As a result, the Company concluded that the proceeds received from the private placement financing cannot be relied upon to mitigate conditions that raise substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within the Company's control. The conversion of the Series C Preferred Stock into common stock and therefore removal of the requirement to make cash payment based on the value of the undelivered shares is subject to a vote of the Company's stockholders.

The Company's ability to satisfy the potential cash settlement obligations associated with the Series C Preferred Stock is not entirely within its control, as it is contingent on, among other things, the Company's ability to obtain stockholder approval and to deliver shares of common stock upon conversion within the timeframes required by the Certificate of Designation. If the Company is unable to obtain stockholder approval in a timely manner, or is otherwise unable to timely deliver shares of common stock upon conversion, holders who submit conversion notices after the applicable trigger date could require the Company to make significant cash payments that could substantially reduce the Company's available cash resources. Factoring in these potential cash payments, based on its current operating plan, the Company believes that its cash and cash equivalents balance will not be sufficient to fund operations and capital expenditures for at least the twelve months following the issuance of these unaudited condensed consolidated financial statements. Accordingly, the Company concluded that substantial doubt about the Company's ability to continue as a going concern continues to exist within one year after the date these financial statements are available to be issued.

The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Note 2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of Quince Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and the notes thereto have been prepared in accordance with GAAP for interim financial information and pursuant to the instructions of the SEC on Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management's opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for the fair statement of the results of operations and cash flows for the periods presented have been included.

The condensed consolidated balance sheet as of June 30, 2026, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2026 and 2025, the condensed consolidated statements of Series C Preferred Stock and stockholders' equity (deficit) for the three and six months ended June 30, 2026 and 2025, the condensed consolidated statements of cash flows for the six months ended June 30, 2026 and 2025, and the financial data and other financial information disclosed in the notes to the condensed consolidated financial statements are unaudited. These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2025 included in the Company's Form 10-K filed with the SEC on April 10, 2026. The results of operations for the three and six months ended June 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim period.

Reverse Stock Splits

On June 29, 2026, the Company effected a 1-for-20 reverse stock split of its outstanding common stock (the "June 2026 Reverse Stock Split"). The June 2026 Reverse Stock Split became effective as of 11:59 p.m., Eastern Time, on June 29, 2026 and the Company's common stock began trading on the Nasdaq Stock Market on a split-adjusted basis on June 30, 2026. The June 2026

Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock.

On April 10, 2026, the Company effected a 1-for-10 reverse stock split of its outstanding common stock (the “April 2026 Reverse Stock Split”). The April 2026 Reverse Stock Split became effective as of 11:59 p.m., Eastern Time, on April 10, 2026 and the Company’s common stock began trading on the Nasdaq Stock Market on a split-adjusted basis on April 13, 2026. The April 2026 Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock.

All share and per share information has been retroactively adjusted to reflect the April and June 2026 Reverse Stock Splits (collectively, the "Reverse Stock Splits") for all periods presented in this report.

Use of Estimates

The preparation of the Company’s condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as related disclosure of contingent assets and liabilities. The most significant estimates used in the Company’s condensed consolidated financial statements relate to the determination of the fair value of identifiable assets and liabilities in connection with business combinations including associated intangible assets, the fair value of contingent consideration, warrant liabilities and debt, accruals for research and development costs, useful lives of long-lived assets, stock-based compensation and related assumptions, the incremental borrowing rate for leases and income tax uncertainties, including a valuation allowance for deferred tax assets, impairment of intangible assets; and contingencies. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes 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. Actual results could differ materially from the Company’s estimates.

Foreign Currency Translation and Transactions

The functional currency of the Company’s wholly-owned international subsidiaries is the Euro. Prior to the dissolution of the Company's Australian subsidiary, the functional currency of that subsidiary was the Australian Dollar. The Company's financial results and financial position are translated into U.S. dollars using exchange rates at balance sheet dates for assets and liabilities and using average exchange rates for income and expenses. The resulting translation differences are presented as a separate component of accumulated other comprehensive loss, as a separate component of equity.

Foreign currency transactions are translated into the functional currencies using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses, resulting from the settlement of such transactions and from the re-measurement of monetary assets and liabilities denominated in foreign currencies using exchange rates at balance sheet date and non-monetary assets and liabilities using historical exchange rates, are recognized in the condensed consolidated statements of operations and comprehensive loss.

Segment Information

The Company manages its business activities on a consolidated basis and operates as one operating and reportable segment, for the purposes of assessing performance and making operating decisions.

Operating segments are defined as components of an enterprise for which discrete financial information is available and is evaluated regularly by the Chief Operating Decision Maker ("CODM"), in deciding how to allocate resources and assess performance.

The Company’s Chief Executive Officer, who is the CODM, reviews financial information on a consolidated basis for purposes of allocating and evaluating financial performance. The CODM evaluates the Company’s performance and resource allocation by analyzing consolidated financial information. See Note 16 for further details.

Business Combination and Asset Acquisitions

The Company evaluates whether an acquisition should be accounted for as a business combination or an asset acquisition under ASC 805, Business Combinations, based on whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. Transactions that do not meet the definition of a business are accounted for as asset acquisitions.

The Company also evaluates whether the acquired entity is a variable interest entity ("VIE") under ASC 810, Consolidation. If the acquired entity is a VIE, the primary beneficiary is identified as the accounting acquirer.

Replacement Awards

When the Company assumes and replaces outstanding stock options of an acquired entity, the fair value of the replacement awards is measured as of the acquisition date using the Black-Scholes option-pricing model. The portion of the fair value attributable to pre-combination service is included in consideration, and the portion attributable to post-combination service is recognized as future compensation expense.

Preferred Stock

The Company assesses its preferred stock to determine whether it should be classified as a liability, mezzanine equity, or permanent equity. This assessment first considers whether the preferred stock meets the definition of a mandatorily redeemable financial instrument or is otherwise required to be classified as a liability under ASC 480, Distinguishing Liabilities from Equity. This includes an evaluation of any provisions labeled as a redemption feature, call option, or conversion option to determine whether the underlying redemption or settlement terms in substance require the Company to redeem the shares.

For preferred stock that is not classified as a liability under ASC 480, the Company assesses whether the preferred stock should be classified as mezzanine equity or permanent equity. This assessment considers whether the preferred stock is redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the Company's control. The Company also considers whether the preferred stock contains liquidation provisions, including fundamental transaction or deemed liquidation provisions, that carry the general characteristics of a redemption feature. Preferred stock that meets any of these conditions is classified as mezzanine equity and presented outside of permanent equity on the Company's condensed consolidated balance sheets. At all other times, the Company classifies its preferred stock in stockholders' equity (deficit).

If the preferred stock is classified as mezzanine equity, the Company further evaluates whether the preferred stock is currently redeemable or probable of becoming redeemable to determine whether the carrying value should be remeasured to its redemption value as of each balance sheet date.

Intangible Assets

Definite lived Intangible Assets

Intangible assets with a definite useful life are amortized on a straight-line basis over the estimated useful life of the related assets. The Company regularly reviews whether current conditions or events suggest that the carrying values of its acquired definite lived intangible assets might not be recoverable. When such conditions are identified, an estimate of the undiscounted future cash flows from these assets, or relevant asset groupings, is compared to their carrying value to determine if an impairment exists. If an

impairment is identified, the loss is calculated as the difference between the carrying value of the intangible asset and its fair value, which is based on the net present value of the estimated future cash flows.

Indefinite lived Intangible Assets

Intangible assets with an indefinite useful life are not amortized. Intangible assets acquired in a business combination or an acquisition that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. Intangible assets acquired in an asset acquisition with no alternative future use are allocated a portion of the consideration transferred and charged to expenses at the acquisition date. Intangible assets acquired in a business combination are initially recorded at fair value. During the period that those assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment. Once the research and development efforts are completed or abandoned, the entity shall determine the useful life of the assets. An indefinite lived intangible asset shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount. If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the intangible asset. Qualitative factors to be considered include but are not limited to:

- Cost factors such as increases in raw materials, labor, or other costs that have a negative effect on future expected earnings and cash flows
- Legal/regulatory factors or progress and results of clinical trials
- Other relevant entity-specific events such as changes in management, key personnel, strategy, or customers; contemplation of bankruptcy; or litigation that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset
- Industry and market considerations such as a deterioration in the environment in which an entity operates, or a more competitive environment
- Macroeconomic conditions such as deterioration in general economic conditions, limitations on accessing capital, fluctuations in foreign exchange rates, or other developments in equity and credit markets that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset.

As a result of the clinical readout of the Phase 3 NEAT study in January 2026, which led the Company to discontinue development of its encapsulated dexamethasone sodium phosphate encapsulated in patient's own red blood cells (“eDSP") product candidate, the research and development associated with the in-process research and development ("IPR&D") was abandoned and an impairment charge recorded to reduce the carrying value to zero.

Intangible assets acquired in an asset acquisition that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts.

Contingent Consideration

The Company determines the fair value of contingent consideration related to the Company's acquisition of EryDel in October 2023 using a probability-weighted discounted cash flow method, with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC Topic 820, Fair Value Measurement. The significant inputs in the Level 3 measurement not supported by market activity include the probability assessments of expected future cash flows, during the contingent consideration period, appropriately discounted considering the uncertainties associated with the earnout obligation, and calculated in accordance with the terms of the definitive agreement. The liability for the contingent consideration were initially

established at the time of the acquisition and are evaluated on a quarterly basis based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the earnings of that period. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Significant increases or decreases in the inputs noted above in isolation would result in a significantly lower or higher fair value measurement. As a result of the clinical readout of the Phase 3 NEAT study in January 2026, which led the Company to discontinue development of eDSP, the criteria for the contingent consideration payments will not be met, resulting in the related liability being reduced to zero.

Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents include marketable securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase and at the end of each reporting period. Investments with maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the balance sheet date are classified as short-term investments. Collectively, cash equivalents and short-term investments are considered available-for-sale and are recorded at fair value. Unrealized gains and losses are recorded as a component of other comprehensive loss in the consolidated statements of operations and included as a separate component of consolidated statements of stockholders' equity. Realized gains and losses are included in interest income in the condensed consolidated statements of operations and comprehensive loss.

Premiums (discounts) are amortized (accreted) over the life of the related investment as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. These amounts are recorded in "interest income" in the condensed consolidated statements of operations and comprehensive loss.

Warrants

The Company accounts for warrants as equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms. The assessment considers whether the warrants are freestanding financial instruments, meet the definition of a liability, and whether the warrants meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are recorded as a component of additional paid-in capital in the condensed consolidated balance sheets at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized within the condensed consolidated statements of operations. The fair value of the warrants is estimated using the Black-Scholes option pricing model (see Note 11).

Reserve for Italian Research and Development Tax Credit

The Company maintains a reserve for Italian research and development tax credits to reflect estimated loss of utilization due to the wind-down of the business. This estimate is based on historical utilization and management's judgment regarding forecasted utilization. Adjustments are recorded in research and development operating expense in the period they become known.

Recently Adopted Accounting Pronouncements

There were no new accounting standards adopted during the three and six months ended June 30, 2026.

Recent Accounting Pronouncements Not Yet Adopted

The following are new accounting pronouncements that the Company is evaluating for future impacts on its financial statements:

ASU 2024-03, *Disaggregation of Income Statement Expenses ("DISE")*. In November 2024, the FASB issued a new accounting standard to improve the disclosures about an entity's expenses and address requests from investors for more detailed information about the types of expenses included in commonly presented expense captions. The new standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with retrospective application permitted. The Company is evaluating the disclosure requirements related to the new standard.

ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements. In December 2025, the FASB issued a new accounting standard to clarify the applicability of interim reporting guidance under GAAP, provide a comprehensive list of interim disclosure requirements within Topic 270, and introduce a disclosure principle requiring entities to provide information about events and changes occurring after the end of the most recent annual reporting period that have a material impact on the entity. The ASU does not change the fundamental nature of interim reporting or expand or reduce existing interim disclosure requirements. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027 for public business entities, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its interim financial reporting and related disclosures.

All other newly issued accounting pronouncements not yet effective have been deemed either immaterial or not applicable.

Note 3. Asset Acquisition

Acquisition of Orphai Therapeutics

On May 18, 2026, the Company acquired Orphai pursuant to that certain Agreement and Plan of Merger, dated May 17, 2026 (the "Merger Agreement"). Under the terms of the Merger Agreement, following closing of the Orphai Acquisition, the Company issued to holders of Orphai, an aggregate of (i) 162,971 shares of the Company's common stock and (ii) 67,101.235 shares of Series C Preferred Stock, each share of which is convertible into 52 shares of common stock, as adjusted for the June 2026 Reverse Stock Split, subject to certain conditions.

Under the terms of the Merger Agreement, options to purchase Orphai common stock were assumed by the Company and were converted into options to purchase an aggregate of 1,308,804 shares of common stock, which options are subject to exercise restrictions prior to obtaining approval during a special meeting of stockholders. In addition, the Company issued to holders of Orphai warrants (the "Acquisition Warrants") to purchase an aggregate of 10,964.505 shares of Series C Preferred Stock (or 570,169 shares on an as-converted-to-common basis, and without giving effect to any beneficial ownership limitations), at an exercise price of $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split).

On May 18, 2026, concurrent with the Orphai Acquisition, the Company entered into a securities purchase agreement (the "May 2026 Securities Purchase Agreement") for a private placement financing with new and returning investors to raise up to $187.0 million in gross proceeds, which includes $115.0 million in upfront proceeds and up to an additional approximately $72.0 million upon exercise of accompanying warrants, in which the investors were issued approximately 144,200.633 shares of Series C Preferred Stock (convertible into an aggregate of 7,498,447 shares of common stock, without giving effect to any beneficial ownership limitations) at a price of $797.50 per share, and accompanying warrants (the "Financing Warrants") to purchase up to 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares, on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at an exercise price of $996.90 per share (or $19.17 per share on an as-converted-to-common basis)

(the "May 2026 Financing"). For additional information relating to the May 2026 Financing, see Notes 4, 9, 10, and 11 to these unaudited condensed consolidated financial statements.

The Orphai Acquisition was accounted for as an asset acquisition as Orphai did not meet the definition of a business under ASC Topic 805, Business Combinations ("ASC 805") as substantially all of its value was in the IPR&D asset. Accordingly, the acquired net assets and assumed net liabilities of Orphai are recorded as of the Orphai Acquisition closing date at their fair value. The Company was determined to be the accounting acquirer based upon the terms of the Orphai Acquisition. Orphai was determined to be a variable interest entity ("VIE") as it was insufficiently capitalized to fund future operations, where the Company is the primary beneficiary. As such, the acquisition costs of $2.1 million were expensed and not capitalized as part of the purchase price in accordance with ASC 805. In addition, the excess of the consideration transferred, and the fair value of the net asset acquired, IPR&D, and net liabilities assumed were recorded as an asset acquisition loss and included in the gain on Orphai Acquisition line item in the condensed consolidated statements of operations and comprehensive loss.

The following table summarizes the estimated fair value of the consideration transferred of $56.9 million (in thousands):

Common stock consideration [(a)]	$	3,242
Preferred stock consideration [(b)]		48,146
Warrant consideration [(c)]		1,315
Assumed share-based awards [(d)]		4,161
Fair value of total consideration transferred	$	56,864

(a) The fair value of consideration transferred was based on 162,971 shares of Common Stock issued multiplied by the closing price of Quince common stock on the acquisition date of May 18, 2026.

(b) The fair value of 67,101.235 shares of Series C Preferred Stock was based on the fair value of the Series C Preferred Stock issued in the May 2026 Financing. For additional information, see Note 9 to these unaudited condensed consolidated financial statements.

(c) The fair value of the warrants issued was determined utilizing the Black-Scholes-Merton option pricing model. Quince issued 10,964.505 warrants of Series C Preferred Stock. For additional information, see Note 11 to these unaudited condensed consolidated financial statements.

(d) Each outstanding and unexercised option award to purchase shares of Orphai common stock was converted into an option award in respect of a number of shares of common stock of the Company. The calculation of consideration transferred includes the portion of the fair-value-based measure of the acquiree awards that relates to the pre-combination service period. The excess value of the replacement Quince awards as well as the fair-value-based measure of the acquiree award related to the post combination service period will be recorded as post combination compensation cost over the remaining service term.

The following table summarizes the allocation of the estimated fair value of the consideration transferred to the net assets acquired and liabilities assumed, with the excess recorded to gain on acquisition (in thousands):

Assets acquired:		
Cash and cash equivalents	$	8,001
Prepaid expenses and other current expenses		451
In-process research and development [(e)]		59,000
Total assets acquired		67,452
Liabilities assumed:		
Trade payables		(3,097)
Accrued expenses and other current liabilities		(6,186)
Total liabilities assumed		(9,283)
Fair value of assets acquired and liabilities assumed		58,169
Gain on Orphai Acquisition	$	1,305

(e) IPR&D represents the research and development projects of Orphai which were in-process, but not yet completed, and which the Company plans to advance. The fair value of IPR&D projects acquired in an asset acquisition with no alternative future use are allocated a portion of the consideration transferred and charged to expenses at the acquisition date.

Note 4. Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the Company estimates that it would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of the assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active.

Level 3 - Inputs that are unobservable. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the six months ended June 30, 2026 and year ended December 31, 2025.

The Company had elected the fair value option for the EIB Loan guaranteed by the Company in connection with the EryDel Acquisition. The Company had adjusted the EIB Loan to fair value through the change in fair value of debt in the accompanying condensed consolidated statements of operations and comprehensive loss. Subsequent unrealized gains and losses on items for which the fair value option is elected were reported in earnings. The Company will break out any change in value due to credit loss in accumulated other comprehensive loss. For the three and six months ended June 30, 2026 and year ended December 31, 2025, there was no change in value due to credit loss.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of June 30, 2026 and December 31, 2025 are presented in the following tables (in thousands):

	Fair Value Measurements as of June 30, 2026			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 114,449	$ 114,449	$ —	$ —
Total Assets	$ 114,449	$ 114,449	$ —	$ —
Liabilities:				
Acquisition Warrants	803	—	—	803
Financing Warrants	5,480	—	—	5,480
Common warrants	9	—	—	9
Total	$ 6,292	$ —	$ —	$ 6,292

	Fair Value Measurements as of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 4,402	$ 4,402	$ —	$ —
Government and agency notes	11,943	—	11,943	—
Total Assets	$ 16,345	$ 4,402	$ 11,943	$ —
Liabilities:				
Short-term contingent consideration	$ 12,369	—	—	12,369
Long-term contingent consideration	51,961	—	—	51,961
Debt	18,026	—	—	18,026
Common warrants	25,452	—	—	25,452
Pre-Funded warrants	6,698	—	—	6,698
Total Liabilities	$ 114,506	$ —	$ —	$ 114,506

The Company classifies government and agency notes as Level 2 investments as the Company uses quoted prices for similar assets sourced from certain third-party pricing services. The third-party pricing services generally utilize industry standard valuation models for which all significant inputs are observable, either directly or indirectly, to estimate the price or fair value of the securities. The primary input generally includes reported trades or quotes on the same or similar securities. The Company does not make additional judgments or assumptions made to the pricing data sourced from the third-party pricing services.

Level 3 Assets and Liabilities

Contingent Consideration

The following table reflects the changes in present value of acquisition related accrued earnouts of contingent consideration liability using significant unobservable inputs (Level 3) for the six months ended June 30, 2026 and 2025 (in thousands):

	June 30, 2026	June 30, 2025
Beginning balance	$ 64,330	$ 56,691
Change in fair value	(64,330)	2,456
Ending balance	$ —	$ 59,147

The contingent consideration arrangement required the Company to pay up to $485.0 million of additional consideration in cash, comprised of up to $5.0 million upon the enrollment of the first patient in the Phase 3 NEAT clinical trial, which was paid in 2024, $25.0 million at NDA acceptance, up to $60.0 million upon the achievement of specified approval milestones, and up to $395.0 million upon the achievement of specified on market and sales milestones. As a result of the clinical readout of the Phase 3 NEAT study in January 2026, which led the Company to discontinue development of eDSP, the criteria for the contingent consideration payments will not be met, resulting in the related liability being reduced to zero during the six months ended June 30, 2026.

To estimate the fair value of the contingent consideration, the Company used a probability-weighted discounted cash flow model with an expected present value valuation technique with significant unobservable fair value inputs and is therefore classified as a Level 3 measurement. The estimates of fair value are uncertain and changes in the estimated inputs may result in significant adjustments to the fair value. The unobservable inputs consisted of the expected timing of milestone completion dates, probability of achievement, and discount rate. The change in the fair value of the contingent consideration during the six months ended June 30, 2025 is primarily due

to the expected timing of achieving various milestones, and the passage of time related to the contingent consideration earnout resulting from the EryDel Acquisition.

The following table summarizes the assumptions used in the valuation of the contingent consideration in the period presented:

	December 31, 2025
Expected timing of milestones completion dates	2026 - 2038
Discount rate	14.2%
Probability of achievement	1% - 56.5%

Debt

The following table presents the changes in the fair value of the Level 3 EIB Loan for the six months ended June 30, 2026 and 2025 (in thousands):

	June 30, 2026	June 30, 2025
Beginning balance	$ 18,026	$ 14,321
Change in fair value	(12,168)	945
Interest payment	(29)	(117)
Settlement of debt	(5,545)	—
Due to foreign currency translation	(284)	1,840
Ending balance	$ —	$ 16,989

To estimate the fair value of the EIB Loan, the Company used an expected present value valuation technique with significant unobservable inputs resulting in classification as a Level 3 measurement. The estimate of fair value is uncertain and changes in the estimated inputs may result in significant adjustments to the fair value. The unobservable inputs consisted of discount rate which includes the credit quality of the Company and credit spreads for comparable debt.

The following table summarizes the assumptions including the unobservable inputs related to the Company's debt in the periods presented:

	December 31, 2025
Discount rate	13%

Acquisition and Financing Warrants

In connection with the Orphai Acquisition, the Company issued to holders of Orphai warrants the Acquisition Warrants to purchase 10,964.505 shares of Series C Preferred Stock (or 570,169 shares on an as-converted-to-common basis, and without giving effect to any beneficial ownership limitations), at an exercise price of $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split).

Concurrent with the May 2026 Securities Purchase Agreement, the Company issued the Financing Warrants to purchase up to 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares, on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at an exercise price of $996.90 per share (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split). Each Financing Warrant will be exercisable beginning on the trading day following the earlier of the Company’s public announcement of (a) top line data from the ongoing LAM-001 Phase 2 trial in Bronchiolitis Obliterans Syndrome (the “LAM-001 Trial”) and (b) the termination or suspension of the LAM-001 Trial and through the 30th day following such public announcement and will be exercisable at a price equal to $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split) for up to an

additional approximately $72.0 million in additional proceeds if exercised in full (with an additional up to $11.0 million in gross proceeds available upon the exercise of warrants issued to former Orphai stockholders).

The Acquisition and Financing Warrants will become exercisable for common stock following the Company's receipt of stockholder approval for the conversion of the Series C Preferred Stock issued in the Orphai Acquisition in accordance with Nasdaq Listing Rules, among other related acquisition matters, subject to certain beneficial ownership limitations.

The Acquisition and Financing Warrants are classified as liabilities on the Company's condensed consolidated balance sheet based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480. See Note 11 for further details. The warrant liability is initially measured at fair value upon issuance and is subsequently remeasured at fair value at each reporting date, with changes in fair value recognized in the condensed consolidated statements of operations.

The Company estimates the fair value of warrants utilizing the Black-Scholes option pricing model, which is dependent upon several Level 3 inputs that are not observable in active markets, including the expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine.

The following table summarizes key inputs used in the valuation of the liability classified Acquisition and Financing Warrants as of the periods presented:

	As of Orphai Acquisition issuance date	As of Private Placement issuance date	As of June 30, 2026
Expected term	0.75 years	0.75 years	0.75 years
Warrant exercise price	$ 19.17	$ 19.17	$ 19.17
Risk-free interest rate	3.70%	3.70%	3.70%
Expected volatility	80.00%	80.00%	80.00%

The following table presents the changes in the fair value of the Level 3 liability classified Acquisition and Financing Warrants for the six months ended June 30, 2026:

	Acquisition Warrants	Financing Warrants
Balance as of December 31, 2025	$ —	$ —
Issuance of warrants	1,315	8,847
Change in fair value of warrants	(512)	(3,367)
Balance as of June 30, 2026	$ 803	$ 5,480

June 2025 Warrants

During the year ended December 31, 2025, in connection with the June 2025 Private Placement (as defined below), the Company issued common and pre-funded warrants (the "June 2025 Warrants") which are classified as liabilities based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 815. See Note 11 for further details. The Company estimated the fair value of the common and pre-funded warrants utilizing the Black-Scholes option pricing model, which was dependent upon several Level 3 inputs that are not observable in active markets, such as expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires judgment to determine. In January 2026, all 10,000 shares of the pre-funded warrants were exercised through a cashless exercise into 9,989 shares of the Company's common stock. In May 2026, the common warrants were terminated as a result of the Orphai Acquisition.

The following table summarizes key inputs used in the valuation of the liability classified June 2025 Warrants as of the period presented:

	As of December 31, 2025
Expected term	4.45 years
Common stock market price	$ 670.00
Common warrants exercise price	$ 240.00
Pre-Funded warrants exercise price	$ 0.20
Risk-free interest rate	3.63%
Expected volatility	110.96%

The following table presents the changes in the fair value of the Level 3 liability classified June 2025 Warrants for the six months ended June 30, 2026:

	(in thousands)
Balance as of December 31, 2025	$ 32,150
Exercise of pre-funded warrants and reclassification to equity	(340)
Payout of common warrants	(57)
Change in fair value of warrants	(31,744)
Balance as of June 30, 2026	$ 9

Note 5. Cash, Cash Equivalents and Investments

The following tables categorize the fair values of cash, cash equivalents and investments measured at fair value on a recurring basis on the condensed consolidated balance sheets (in thousands):

	June 30, 2026	December 31, 2025
Cash and cash equivalents:		
Cash	$ 1,532	$ 1,407
Money market funds	114,449	4,402
Total cash and cash equivalents	$ 115,981	$ 5,809
Short-term investments:		
Government and agency notes	—	11,943
Total short-term investments	$ —	$ 11,943

The Company's investments are classified as available-for-sale securities. As of June 30, 2026, there were no available-for-sale securities outstanding. There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale securities for the three and six months ended June 30, 2026 and 2025, and as a result, the Company did not reclassify any significant amounts out of accumulated other comprehensive loss. No other-than-temporary impairments on these securities were recognized for the three and six months ended June 30, 2026 and 2025.

The Company periodically assesses its investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses is determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. There have been no impairments or credit losses related to available-for-sale securities for the three and six months ended June 30, 2026 and 2025.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security’s amortized cost basis is written down to fair value and recognized in interest and other income, net in the statement of operations and comprehensive loss. If neither criteria is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions

specifically related to the security, among other factors. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in other income (expense), net.

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income, net of tax as a separate component of stockholders' equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income (expense), net in the condensed consolidated statement of operations and comprehensive loss.

For purposes of identifying and measuring credit-related impairments, the Company's policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded in other current assets on the condensed consolidated balance sheets.

The following table summarizes the available-for-sale securities (in thousands):

	Fair Value Measurements as of June 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 114,449			$ 114,449
Total cash equivalents and investments	$ 114,449	—	$ —	$ 114,449
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 114,449
Total cash equivalents and investments				$ 114,449

	Fair Value Measurements as of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 4,402	$ —	$ —	$ 4,402
Government and agency notes	11,938	5	—	11,943
Total cash equivalents and investments	$ 16,340	$ 5	$ —	$ 16,345
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 4,402
Short-term investments (maturities within one year)				11,943
Total cash equivalents and investments				$ 16,345

Note 6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Prepaid research and development expenses	$ 1,269	$ 578
Short-term Italian research and development tax credit, net	229	—
Short-term VAT receivable, net	4,773	3,622
Prepaid insurance	272	635
Prepaid expenses	494	255
Other current assets	393	54
Total prepaid expenses and other current assets	$ 7,430	$ 5,144

The Company was eligible to obtain an R&D tax credit as companies in Italy that invest in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from an R&D tax credit. Such tax credits can only be used to offset payments of certain taxes and contributions (e.g., social contributions, VAT payables, registration fees, income and withholding taxes and other tax-related items that companies usually pay monthly). During the three and six months ended June 30, 2026, the Company recorded no increases to R&D tax credit and $3.0 million increase to R&D tax credit balance due to the release of Italy-related unrecognized tax benefits. During the three and six months ended June 30, 2026, the Company utilized $1.5 million and $2.1 million of R&D tax credit towards related tax payable and payroll-related tax expenses. The Company recorded an adjustment to reduce the reserve for estimated credits that were not probable of being used of $0.4 million for a total of $0.7 million reserved based on forecasted utilization in Italy as of June 30, 2026.

During the three and six months ended June 30, 2026, the Company recorded a $0.5 million reserve for estimated VAT receivable that are not probable of being recovered.

The Company recognized a total reduction to R&D expense of $0.1 million and $1.2 million for the three and six months ended June 30, 2026, and reductions to R&D expense of $0.6 million and $0.9 million for the three and six months ended June 30, 2025.

The balance in the reserve for Italian research and development tax credit and reserve for VAT receivable for the six months ended June 30, 2026 is as follows (in thousands):

	Reserve for Italian research and development tax credit	Reserve for VAT receivable
Beginning balance as of December 31, 2025	$ —	$ —
Change in reserve	(649)	(515)
Ending balance as of June 30, 2026	$ (649)	$ (515)

Other Assets

Other assets consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Long-term VAT receivable	$ —	$ 1,682
Equity investments in Lighthouse Pharmaceuticals, Inc.	78	78
Total other assets	$ 78	$ 1,760

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Computer equipment	$ 61	$ 66
Computer software	38	32
Lab equipment	1,031	1,076
Leasehold improvement	37	38
Office furniture	221	227
Less: accumulated amortization and depreciation	(882)	(844)
Property and equipment, net	$ 506	$ 595

Accrued Expenses and Other Current Liabilities

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

	June 30, 2026	December 31, 2025
Personnel expenses	$ 1,762	$ 3,138
Research and development expenses	722	6,966
Professional fees	1,016	181
Current portion of operating lease liabilities	—	115
Other	364	208
Total accrued expenses and other current liabilities	$ 3,864	$ 10,608

During the six months ended June 30, 2026, the Company entered into settlement agreements with vendors pursuant to which they relinquished amounts owed by the Company. This resulted in a $3.7 million gain on settlement of accounts payable for the six months ended June 30, 2026, which is reflected in the condensed consolidated statements of operations and comprehensive loss within research and development.

For the six months ended June 30, 2026 and 2025, the severance accrual activity was as follows (in thousands):

	For the Six Months Ended June 30,	
	2026	2025
Beginning accrued severance	$ 42	$ —
Incurred during the period	2,251	413
Severance paid during the period	(2,293)	(168)
Ending accrued severance	$ —	$ 245

During the six months ended June 30, 2026 and 2025, the Company incurred severance costs related to personnel separation, reflecting payments made and accrued to departing employees.

Other Long-Term Liabilities

Other long-term liabilities consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Federal and state taxes payable	$ 540	$ 773
Foreign taxes payable	103	691
Other long-term liabilities	73	106
Other long-term liabilities	$ 716	$ 1,570

Note 7. Leases

In January 2024, the Medolla Lease Agreement for the office space was renegotiated. The new Medolla Lease Agreement includes an additional space and commenced on February 1, 2024, to end on January 31, 2030, substituting the Medolla Lease Agreement commenced in June 2018. In June 2026, the Medolla Lease was terminated, and the Company recognized an immaterial loss in connection with the termination.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. During the three and six months ended June 30, 2026, the Company recorded lease expense of $43 thousand and $80 thousand, respectively. During the three and six months ended June 30, 2025, the Company recorded lease expense of $38 thousand and $76 thousand, respectively.

Supplemental balance sheet information related to leases as follows (in thousands except lease terms and discount rates):

	December 31, 2025
Assets:	
Operating lease right of use asset, net	$ 453
Liabilities:	
Short-term operating lease liability	115
Long-term operating lease liability	330
Total lease liabilities	$ 445
Other information:	
Weighted average remaining lease term	3.7 years
Weighted average discount rate	9.12%

There are no future minimum lease payments under lease agreements as of June 30, 2026.

Note 8. Debt

In connection with the acquisition of EryDel on October 20, 2023, the Company became a guarantor in respect of the EIB Loan. The EIB Loan was amended and restated as of the acquisition date. The EIB Loan provided for maximum borrowings of 30.0 million euro through four tranches; tranche A, 3.0 million euro; tranche B, 7.0 million euro; tranche C, 10.0 million euro; and tranche D, 10.0 million euro. Each tranche was subject to conditions precedent related to the Company's business and capitalization. Only tranches A and B were drawn. All amounts due under tranche A and B were payable on their maturity date of August 2026. Interest accrued at fixed rates for each tranche and was payable on the maturity date for each Tranche (with the exception of 2% cash interest which was accrued and payable quarterly during fiscal year 2025 pursuant to the terms of the Amendment, which correspondingly reduced the deferred interest rate accruing during such period). The fixed rates ranged from 7.0% to 9.0% per annum.

The Company had elected to account for the EIB Loan at fair value, which required the EIB Loan to be recorded at fair value at issuance and at the end of each reporting period. Gains or losses upon remeasurement were recorded in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company presented separately in other comprehensive loss the portion of the total change in the fair value of the EIB Loan that results from a change in instrument-specific credit risk. The EIB Loan's fair value at the date it was assumed adjusted its carrying value based on using a discounted cash flow analysis with a discount rate based on a yield curve that was adjusted for credit rating.

In March 2026, the EIB agreed to a full settlement of all obligations associated with the loan with a single payment of 4.8 million euros ($5.5 million) which was paid on March 30, 2026.

For the six months ended June 30, 2026, the Company paid 25 thousand euros ($29 thousand) in interest payments.

Note 9. Series C Preferred Stock

Series C Preferred Stock

On May 18, 2026, the Company filed the Certificate of Designation with the Secretary of State of the State of Delaware in connection with the Orphai Acquisition. The Certificate of Designation provides for the authorization of 294,370 shares of Series C Preferred Stock, of which 67,101.235 shares were issued as merger consideration in connection with the Orphai Acquisition, and 144,200.633 shares were issued in the concurrent May 2026 Financing.

Holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock (on an as-converted basis) equal to and in the same form as dividends paid on shares of the Company's common stock.

Except as otherwise provided in the Certificate of Designation or as otherwise required by the Delaware General Corporation Law of the State of Delaware, the Series C Preferred Stock has no voting rights and no rights to elect directors.

Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary, each holder of Series C Preferred Stock is entitled to receive out of the assets of the Company the same amount that a holder of common stock would receive if the Series C Preferred Stock were converted to common stock, paid pari passu with the holders of common stock. If the assets of the Company are insufficient to pay the holders of Series C Preferred Stock in full, all remaining assets of the Company are distributed ratably to the holders of Series C Preferred Stock and the holders of common stock in accordance with their respective amounts.

The Series C Preferred Stock is not redeemable. However, if, at any time after the earlier of (i) stockholder approval of the Company Stockholder Matters or (ii) six months after the initial issuance of the Series C Preferred Stock, the Company fails to deliver conversion shares to a holder as required, the Company is required, at the request of the holder, to pay cash equal to the fair value of such undelivered shares.

Effective upon Stockholder Approval, each share of Series C Preferred Stock will automatically convert into 52.00 shares of Common Stock, as adjusted for the June 2026 Reverse Stock Split. Prior to that, each share of Series C Preferred Stock is convertible into 52.00 shares of Common Stock at the option of the holder, as adjusted for the June 2026 Reverse Stock Split, at any time following the earlier of (i) Stockholder Approval or (ii) six months after the initial issuance of the Series C Preferred Stock.

Given the cash settlement feature described above and the fundamental transaction provisions of the Series C Preferred Stock, the Series C Preferred Stock was classified as mezzanine equity on the condensed consolidated balance sheets.

Note 10. Stockholders’ Equity

Common Stock

On June 4, 2025, the Company’s shareholders approved an amendment to the Company’s certificate of incorporation to increase the total number of authorized shares of Common Stock from 100,000,000 to 250,000,000. The Reverse Stock Splits did not affect the number of authorized shares of common stock or the par value of the common stock.

ATM Program

On December 18, 2024, the Company entered into a Controlled Equity Offering[SM] Sales Agreement, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the "Agents"), relating to the sale of shares of the Company's common stock. In accordance with the terms of this agreement, the Company may offer and sell up to $75.0 million shares of common stock.

During the six months ended June 30, 2026, the Company utilized its ATM program to raise net proceeds of approximately $20.3 million by issuing 526,435 shares of common stock. As of June 30, 2026, $47.5 million remained available to be utilized under the ATM program.

May 2026 Private Placement

On May 18, 2026, concurrent with the Orphai Acquisition, the Company entered into the May 2026 Securities Purchase Agreement for a private placement financing with new and returning investors to raise up to $187.0 million in gross proceeds, which includes $115.0 million in gross upfront proceeds, net of $11.4 million of offering costs, commissions, legal and other expenses for net proceeds from the offering of $103.6 million, and up to an additional approximately $72.0 million upon exercise of the Financing Warrants, in which the investors were issued approximately 144,200.633 shares of Series C Preferred Stock (convertible into an aggregate of 7,498,447 shares of common stock, without giving effect to any beneficial ownership limitations) at a price of $797.50 per share and Financing Warrants to purchase up to 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares, on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at an exercise price of $996.90 per share (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split). For additional information, see Note 3, 9, and 11 to these unaudited condensed consolidated financial statements.

June 2025 Private Placement

On June 12, 2025, the Company entered into a Securities Purchase Agreement (the “June 2025 Securities Purchase Agreement”), with certain institutional investors (the “Investors”) and certain members of the Company’s management (together with the Investors, the “June 2025 Purchasers”) pursuant to which the Company issued and sold to the June 2025 Purchasers in a private placement (“June 2025 Private Placement”): (i) 33,360 shares (the “Shares”) of its common stock, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to an aggregate of 10,000 shares of common stock, and (iii) accompanying warrants to purchase up to an aggregate of 43,360 shares of common stock (the “Common Warrants”), for aggregate gross proceeds of approximately $11.5 million (excluding up to approximately $10.4 million of aggregate gross proceeds that may be received in the future upon the cash exercise in full of the Common Warrants issued in the June 2025 Private Placement), before deducting placement agent fees and other expenses payable by the Company. In May 2026, all of the Common Warrants issued in connection with the June 2025 Private Placement were terminated in connection with the consummation of the Orphai Acquisition.

Note 11. Warrants

Acquisition and Financing Warrants

On May 18, 2026, under the Merger Agreement, the Company issued Acquisition Warrants to holders of Orphai warrants to purchase up to an aggregate of 10,964.505 shares of Series C Preferred Stock (or 570,169 shares on an as-converted-to-common basis, without giving effect to any beneficial ownership limitations), at an exercise price of $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split). In addition, on May 18, 2026, concurrent with the Orphai Acquisition, in connection with the May 2026 Financing, the Company issued Financing Warrants to investors in the May 2026 Financing to purchase up to an aggregate of 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares on an as-converted-to-common basis, without giving effect to any beneficial ownership limitations), at an exercise price of $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split).

In the aggregate, the Company issued warrants to purchase up to 83,064.827 shares of Series C Preferred Stock (or 4,319,400 shares on an as-converted-to-common basis).

The Acquisition and Financing Warrants do not become exercisable until the trading day following the earlier of the Company's public announcement of (a) top line data from the LAM-001 Trial or (b) the termination or suspension of the LAM-001 Trial, and remain exercisable only through the 30th day following such announcement. Prior to the Company's receipt of stockholder approval for the conversion of the Series C Preferred Stock issued in the Orphai Acquisition in accordance with Nasdaq Listing Rules, the Acquisition and Financing Warrants are exercisable only into shares of Series C Preferred Stock, which is itself subject to certain beneficial ownership limitations established by each holder. As a result of these provisions, the warrants fail the indexation guidance under ASC 815 and are classified as liabilities. The Acquisition and Financing Warrant liability was recorded at fair value as of the issuance date and is subject to remeasurement to estimated fair value at each balance sheet date until the warrants are exercised or expire, with changes in fair value recognized in the condensed consolidated statements of operations.

The proceeds from the May 2026 Financing were first allocated to the full fair value of the Financing Warrants due to the liability classification. The fair value of the Financing Warrants at issuance was $11.5 million. The remaining proceeds of $103.5 million, before issuance costs, were allocated to the Series C Preferred Stock.

As of June 30, 2026, none of the Acquisition and Financing Warrants had been exercised, and 83,064.827 shares underlying the Acquisition and Financing Warrants remained outstanding. The following table is a summary of the Company's Acquisition and Financing Warrants outstanding as of June 30, 2026:

	Number of Common Stock Issuable		Exercise Price
Acquisition Warrants	570,169	$	19.17
Financing Warrants	3,749,231	$	19.17

Common and Pre-Funded Warrants

On June 12, 2025, in connection with the sale and issuance of common stock as part of the June 2025 Private Placement, the Company issued Pre-Funded Warrants to purchase up to an aggregate of 10,000 shares of common stock at an exercise price of $0.20 per share and Common Warrants to purchase up to an aggregate of 43,360 shares of common stock at an exercise price of $240.00 per share. Each Share and each Pre-Funded Warrant sold pursuant to the June 2025 Securities Purchase Agreement was accompanied by one Common Warrant. The combined purchase price of each Share and accompanying Common Warrant was $265.00 (which included $25.00 per Common Warrant in accordance with the rules and regulations of Nasdaq). The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrant was $264.80 (equal to the combined purchase price per Share and accompanying Common Warrant, minus $0.20).

The Common Warrants can be exercised into either common stock or Pre-Funded Warrants at the holders' option, and both Common Warrants and Pre-Funded Warrants contain purchase rights that could result in holders receiving securities that more than offsets or neutralizes the effect of a distribution event. As a result of the aforementioned provisions, both Common Warrants and Pre-Funded Warrants fail the indexation guidance under ASC 815 and are classified as liabilities. The Pre-Funded Warrants and Common Warrants liabilities were recorded at fair value as of the issuance date and June 30, 2026, and subject to adjustment to estimated fair value at each balance sheet date until the warrants are settled.

The proceeds from June 2025 Private Placement were first allocated to the full fair value of the Pre-Funded Warrants and Common Warrants due to the liability classification. The fair value of the Pre-Funded Warrants and Common Warrants at issuance was $10.7 million. The remaining proceeds of $0.8 million, before issuance costs, were allocated to the common stock.

During the three and six months ended June 30, 2026, the Company recognized a fair value gain of $4.5 million and $35.6 million, respectively, related to the total warrants.

On January 29, 2026, all 10,000 shares of the Pre-Funded Warrants were exercised through a cashless exercise into 9,989 shares of the Company's common stock. In May 2026, all of the Common Warrants issued in connection with the June 2025 Private Placement were terminated in connection with the consummation of the Orphai Acquisition.

Note 12. Stock-Based Compensation

The Company operates three stock-based compensation plans as of June 30, 2026:

- 2019 Equity Incentive Plan (Quince)
- 2019 Equity Incentive Plan (Novosteo)
- 2022 Inducement Plan (Quince)
- 2013 Orphai Plan (Orphai)
- 2026 Orphai Plan (Orphai)

2019 Equity Incentive Plan (Quince)

On December 4, 2014, the Company's stockholders approved the 2014 Stock Plan ("2014 Plan"), and on April 25, 2019 amended, restated and re-named the 2014 Plan as the 2019 Equity Incentive Plan (the "Quince 2019 Plan"), which became effective as of May 7, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. The remaining shares available for issuance under the 2014 Plan were added to the shares reserved for issuance under the Quince 2019 Plan.

The Quince 2019 Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Company's employees, directors, and consultants. As of June 30, 2026, the maximum aggregate number of shares that may be issued under the Quince 2019 Plan is 78,309 shares of the Company's common stock. In addition, the number of shares available for issuance under the Quince 2019 Plan will be annually increased on the first day of each fiscal years beginning with fiscal 2020, by an amount equal to the least of (i) 10,732 shares of common stock; (ii) 4% of the outstanding shares of its common stock as of the last day of its immediately preceding fiscal year; and (iii) such other amount as the Board of Directors may determine.

The Quince 2019 Plan may be amended, suspended or terminated by the Board of Directors at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the Quince 2019 Plan as required by applicable law or listing requirements. Unless sooner terminated by the Company's Board of Directors, the Quince 2019 Plan will automatically terminate on April 23, 2029.

As of June 30, 2026, the Company had 10,510 shares available for future issuance under the Quince 2019 Plan.

Stock Options

Stock options under the Quince 2019 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant. If, at the time of grant, the optionee directly owns stocks representing more than 10% of the voting power of all our outstanding capital stock, the exercise price for these options must be at least 110% of the fair value of the underlying common stock. Stock options granted to employees and non-employees generally have a maximum term of ten years and vest over four years from the vesting commencement date, of which 25% vest on the one-year anniversary of the vesting commencement date, and 75% vest in equal monthly installments over the remaining three years or monthly vesting over 3 to 4 years. We may grant options with different vesting terms from time to time. Unless an employee's or non-employee's termination is due to cause, disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the termination date or expiration of the option, whichever is earlier.

Activity for service-based stock options under the Quince 2019 Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance as of December 31, 2025	**51,454**	$ 546.01	6.79	$ 18,844
Options granted	14,174	604.12	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(8,598)	830.44	—	—
Balance as of June 30, 2026	**57,030**	$ 517.57	7.71	$ —
Options vested and expected to vest as of June 30, 2026	57,030	517.57	7.71	—
Options exercisable as of June 30, 2026	29,276	$ 622.97	6.83	$ —

For the three and six months ended June 30, 2026, the Company recognized stock-based compensation expense of $0.7 million and $1.6 million, respectively, related to options granted to employees and non-employees. For the three and six months ended June 30, 2025, the Company recognized stock-based compensation expense of $0.8 million and $1.7 million, respectively, related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements. As of June 30, 2026, total unamortized employee stock-based compensation was $7.2 million, which is expected to be recognized over the remaining estimated vesting period of 1.2 years.

The weighted average grant date fair value per share of stock options granted during the six months ended June 30, 2026 and 2025 was $507.87 and $419.35, respectively.

For the six months ended June 30, 2026, in connection with the separation of employees as part of our restructuring activities, the Company extended the post-termination exercise window from 90 days to five years for separated employees and for those with consulting agreements allowed awards to continue vesting through term of the agreements. The Company recorded stock-based compensation expense related to the modification of these awards of $0.1 million.

2019 Equity Incentive Plan (Novosteo)

On May 19, 2022, in accordance with the terms of Agreement and Plan of Merger and Reorganization between the Company, Novosteo, Inc., and the other parties thereto, the Company assumed the 2019 Novosteo, Inc. Equity Incentive Plan (the "2019 Novosteo Plan"). The 2019 Novosteo Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Novosteo legacy employees. On the closing date, each outstanding Novosteo stock option granted under Novosteo's equity compensation plans was converted into a corresponding stock option with the number of shares underlying such option and the applicable exercise price adjusted based on the exchange ratio of 0.0911. Each such converted stock option continues to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo stock option prior to the acquisition. The maximum aggregate number of shares that may be issued under the 2019 Novosteo Plan is 2,725 shares of the Company's common stock.

The 2019 Novosteo Plan may be amended, suspended or terminated by the Board of Directors at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the 2019 Novosteo Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board of Directors, the 2019 Novosteo Plan will automatically terminate on May 20, 2029.

Stock options under the 2019 Novosteo Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant. If, at the time of grant, the optionee directly owns stocks representing more than 10% of the voting power of all our outstanding capital stock, the exercise price for these options must be at least 110% of the fair value of

the underlying common stock. Stock options granted to employees and non-employees generally have a maximum term of ten years and vest over four years from the vesting commencement date, of which 25% vest on the one-year anniversary of the vesting commencement date, and 75% vest in equal monthly installments over the remaining three years or monthly vesting over 3 to 4 years. We may grant options with different vesting terms from time to time. Unless an employee's or non-employee's termination is due to cause, disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the termination date or expiration of the option, whichever is earlier.

As of June 30, 2026, the Company had 960 shares available for future issuance under the 2019 Novosteo Plan.

Activity for service-based stock options under the 2019 Novosteo Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance as of December 31, 2025	**808**	$ 110.00	6.23	$ 451
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of June 30, 2026	**808**	$ 110.00	5.73	$ —
Options vested and expected to vest as of June 30, 2026	808	110.00	5.73	—
Options exercisable as of June 30, 2026	806	$ 110.00	5.73	$ —

For the three and six months ended June 30, 2026, the Company recognized stock-based compensation expense of $0 and $44 thousand, respectively, related to options granted to employees and non-employees for the 2019 Novosteo Plan. For the three and six months ended June 30, 2025, the Company recognized stock-based compensation expense of $48 thousand and $97 thousand, respectively, related to options granted to employees and non-employees for the 2019 Novosteo Plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements. As of June 30, 2026, there was no total unamortized employee stock-based compensation.

Restricted Stock Awards

There was no restricted stock awards activity during the six months ended June 30, 2026.

For the three and six months ended June 30, 2026, the Company recognized no stock-based compensation expense related to restricted stock awards. For the three and six months ended June 30, 2025, the Company recognized stock-based compensation expense of $0.1 million and $0.2 million related to restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the award holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. The fair value of vested restricted stock awards was $0.1 million and $0.2 million for the three and six months ended June 30, 2025, respectively.

2022 Inducement Plan

On May 9, 2022, the Company's Board of Directors approved 20,000 shares of common stock, that may be offered or issued under the Quince Therapeutics, Inc. 2022 Inducement Plan (the "2022 Inducement Plan"). The 2022 Inducement Plan was adopted by the independent members of the Board of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules (“Nasdaq Rule 5635(c)(4)”). In accordance with Nasdaq Rule 5635(c)(4), awards under those plans may only be made to an employee who has not previously been an employee or member of the Board of Directors or of any board of directors of any parent or subsidiary of the Company, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted

such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The terms and conditions of the 2022 Inducement Plan are substantially similar to those of the Quince 2019 Plan.

Options under the 2022 Inducement Plan may be granted for periods of up to 10 years at prices no less than 100% of the fair market value of the shares on the date of grant. Options granted to employees may have different performance goals or other vesting provisions (including continued employment) in accordance with the applicable award agreement. Unless an employee's termination service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the date of termination or expiration of the option, whichever is earlier.

As of June 30, 2026, the Company had 8,333 shares available for future issuance under the 2022 Inducement Plan.

Activity for service-based stock options under the 2022 Inducement Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value (In thousands)
Balance as of December 31, 2025	**11,667**	$ 596.00	6.39	863
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of June 30, 2026	**11,667**	$ 596.00	5.90	—
Options vested and expected to vest as of June 30, 2026	11,667	596.00	5.90	—
Options exercisable as of June 30, 2026	11,667	$ 596.00	5.90	—

For the three and six months ended June 30, 2026, the Company recognized stock-based compensation expense of $0.2 million and $0.5 million, respectively, related to options granted to employees for the 2022 Inducement Plan. For the three and six months ended June 30, 2025, the Company recognized stock-based compensation expense of $0.3 million and $0.7 million, respectively, related to options granted to employees for the 2022 Inducement Plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements. As of June 30, 2026, there was no total unamortized employee stock-based compensation.

Orphai Equity Incentive Plans

In connection with the Orphai Acquisition, the Company assumed all outstanding and unexercised stock options previously granted by Orphai under its 2013 Employee, Director, and Consultant Equity Incentive Plan (the "2013 Orphai Plan"), as amended, and its 2026 Stock Incentive Plan (the "2026 Orphai Plan") (collectively, the "Orphai Equity Incentive Plans"), whether or not vested as of the acquisition date.

Under the terms of the Merger Agreement, each Orphai stock option was converted into an option to purchase shares of the Company's common stock, with (i) the number of shares subject to each option determined by multiplying the number of shares subject to the original Orphai option by an exchange ratio of 0.6935, rounded down to the nearest whole share, and (ii) the per-share exercise price determined by dividing the original per-share exercise price by the same exchange ratio. The vesting schedule and remaining contractual term of each replacement award were not modified in connection with the assumption, and no vesting was accelerated.

Activity for service-based stock options under the 2013 Orphai Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value (In thousands)
Balance as of December 31, 2025	—	$ —	—	—
Options assumed	118,257	17.99	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of June 30, 2026	**118,257**	$ 17.99	5.80	1,633
Options vested and expected to vest as of June 30, 2026	118,257	17.99	5.80	1,633
Options exercisable as of June 30, 2026	112,210	$ 18.85	5.65	1,535

For the three and six months ended June 30, 2026, the Company recognized stock-based compensation expense of $0.5 million, related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements. As of June 30, 2026, total unamortized employee stock-based compensation was $0.1 million, which is expected to be recognized over the remaining estimated vesting period of 0.13 years.

The weighted average grant date fair value per share of stock options assumed during the six months ended June 30, 2026 was $19.59.

Activity for service-based stock options under the 2026 Orphai Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value (In thousands)
Balance as of December 31, 2025	—	$ —	—	—
Options assumed	1,190,547	14.71	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of June 30, 2026	**1,190,547**	$ 14.71	9.84	$ 4,141
Options vested and expected to vest as of June 30, 2026	1,190,547	14.71	9.84	4,141
Options exercisable as of June 30, 2026	657,144	$ 13.28	9.84	$ 3,224

For the three and six months ended June 30, 2026, the Company recognized stock-based compensation expense of $10.7 million, related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements. As of June 30, 2026, total unamortized employee stock-based compensation was $10.5 million, which is expected to be recognized over the remaining estimated vesting period of 1.38 years.

The weighted average grant date fair value per share of stock options assumed during the six months ended June 30, 2026 was $19.80.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the three and six months ended June 30, 2026 and 2025 and the allocation within the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
General and administrative expense	$ 8,911	$ 835	$ 9,655	$ 1,785
Research and development expense	3,182	438	3,724	874
Total stock-based compensation	$ 12,093	$ 1,273	$ 13,379	$ 2,659

Note 13. Income Taxes

After considering all available positive and negative evidence, including cumulative losses, the Company concluded that it remains more likely than not that its net deferred tax assets will not be realized. Accordingly, the Company maintains a full valuation allowance against its net deferred tax assets.

The Company recorded an income tax expense of $0.1 million for the three months ended June 30, 2026 and income tax benefit of $5.3 million for the six months ended June 30, 2026, primarily related to the discrete reversal of uncertain tax position liabilities associated with certain intellectual property following changes in facts and circumstances in the six months ended June 30, 2026 that affected the valuation of the intellectual property. This benefit was partially offset by current-period Italian income tax expense. The primary differences between the Company's effective tax rate and the U.S. federal statutory tax rate were the change in valuation allowance and the discrete reversal of uncertain tax position liabilities.

The Company recorded $67 thousand and $0.1 million of tax expense for the three and six months ended June 30, 2025, respectively, primarily related to foreign withholding tax and interest on the uncertain tax position liability.

Note 14. Net Loss Per Share

Basic net loss per common share is determined by dividing the net loss by the weighted-average common shares outstanding during the period. The preferred shares do not have substantive preferential rights over common shares and are considered in-substance common shares and treated as a separate class of common stock for the purposes of computing earnings per share.

Basic and diluted net loss per common share is determined by dividing the net loss by the weighted-average common shares outstanding during the period, as follows (net loss in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (75,488)	$ (16,049)	$ (39,576)	$ (31,079)
Denominator:				
Weighted average shares of common stock and in-substance common stock outstanding	6,132,845	233,431	3,295,727	226,571
Net loss per share – basic and diluted	$ (12.31)	$ (68.75)	$ (12.01)	$ (137.17)

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	June 30,	
	2026	2025
Stock options issued and outstanding	1,378,309	64,000
Common warrants	—	43,360
Acquisition Warrants	570,169	—
Financing Warrants	3,749,231	—
Pre-funded warrants	—	10,000
Restricted stock awards	—	149
Total	5,697,709	117,509

Note 15. Intangible Assets

EryDel Intangible Assets

The following table provides details of the carrying amount of the Company's indefinite-lived intangible asset (in thousands):

	(in thousands)
In-process research and development:	
Balance as of December 31, 2025	$ 67,361
Impairment charges	(67,361)
Balance as of June 30, 2026	$ —

The following table provides details of the carrying amount of the Company's finite-lived intangible asset (in thousands, except useful life):

		As of June 30, 2026			As of December 31, 2025		
	Useful life	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite life intangible assets:							
Trade name	21 years	$ 460	(49)	$ 411	$ 460	(26)	$ 434
Foreign currency translation adjustments				36			(8)
Impairment charges				(447)			—
Total				$ —			$ 426

In January 2026, the Company ceased clinical development of eDSP as the primary and secondary endpoints did not achieve statistical significance in its Phase 3 NEAT clinical trial. As a result, several of the assumptions used in determining the initial fair value have changed including expected cash flows and thus triggered the need for an interim impairment assessment as required under ASC 350. As a result, the fair value was determined to be significantly below its carrying value and the Company recognized a total impairment charge of $67.8 million for indefinite and finite-lived intangible assets during the six months ended June 30, 2026.

Note 16. Segment Information

The Company manages its business activities on a consolidated basis and operates as one operating and reportable segment for the purposes of assessing performance and making operating decisions.

Operating segments are defined as components of an enterprise for which discrete financial information is available and is evaluated regularly by the CODM, in deciding how to allocate resources and assess performance.

The Company’s Chief Executive Officer, who is the CODM, reviews financial information on a consolidated basis for purposes of allocating and evaluating financial performance. The CODM evaluates the Company’s performance and resource allocation by analyzing consolidated net loss, as reported on the condensed consolidated statement of operations and comprehensive loss. This assessment involves comparing net loss across prior periods, the Company's forecast, and following the Orphai Acquisition, total expenditures related to LAM-001 product development.

The measure of segment assets reviewed by the CODM is the consolidated total assets, as reported on the condensed consolidated balance sheets. The following table presents the measure of segment assets regularly provided to the CODM (in thousands):

	June 30, 2026	December 31, 2025
Cash, cash equivalents and short-term investments	115,981	17,752

The following table presents financial information, including significant segment expenses, which are regularly provided to the CODM and included within condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development:				
Personnel	$ 2,105	$ 1,294	$ 4,019	$ 2,614
Stock-based compensation	3,182	438	3,724	873
Clinical and contract manufacturing	1,173	5,342	4,773	12,069
Other	(999)	(521)	(210)	(858)
General and administrative:				
Personnel	2,102	1,038	3,438	2,765
Stock-based compensation	8,911	834	9,655	1,785
Consulting and professional costs	4,981	786	6,539	2,252
Other	632	684	1,261	1,329
Acquired in-process research and development	59,000	—	59,000	—
Gain on Orphai Acquisition	(1,305)	—	(1,305)	—
Intangible asset impairment charge	—	—	67,808	—
Fair value adjustment for contingent consideration	—	532	(64,330)	2,456
Total operating expenses	79,782	10,427	94,372	25,285
Loss from operations	(79,782)	(10,427)	(94,372)	(25,285)
Fair value adjustment for debt	—	(501)	12,168	(945)
Fair value adjustment for warrants	4,507	(4,464)	35,623	(4,464)
Warrant issuance costs	(874)	(872)	(874)	(872)
Other segment items	661	215	7,879	487
Net loss	$ (75,488)	$ (16,049)	$ (39,576)	$ (31,079)

Other segment items within net loss include interest income, other income (expense), net, and income tax expense.

The Company’s long-lived assets consist primarily of property, plant and equipment, net, and operating lease right-of-use assets are maintained in Italy. As of June 30, 2026 and December 31, 2025, no individual country other than the U.S. accounted for 10% or more of these assets.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes, included in "Part I. Item 1. Financial Statements" of this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions, that are based on the beliefs of our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, as well as our Amendment No. 2 to Current Report on Form 8-K filed with the SEC on July 30, 2026. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "Quince," "we," "us," and "our" refer to Quince Therapeutics, Inc. and its consolidated subsidiaries, including Orphai Therapeutics, for periods after the Orphai Acquisition.

Unless otherwise indicated, all share and per share information has been retroactively adjusted to reflect the 1-for-10 reverse stock split of our common stock that became effective on April 10, 2026 (the "April 2026 Reverse Stock Split") and the 1-for-20 reverse stock split of our common stock that became effective on June 29, 2026 (the "June 2026 Reverse Stock Split" and, together with the April 2026 Reverse Stock Split, the "Reverse Stock Splits").

Overview

We are a clinical-stage biopharmaceutical company developing a novel disease modifying therapeutic to address the significant unmet medical need associated with pulmonary disorders with few, if any, treatment options available.

On May 18, 2026, we completed the acquisition of Orphai Therapeutics, LLC, a clinical-stage biotechnology company developing a novel disease modifying therapeutic to address the significant unmet medical need associated with pulmonary disorders with few, if any, treatment options available, in accordance with the terms of the Agreement and Plan of Merger, dated May 17, 2026 (the "Merger Agreement"), by and among the Company, Orphai, and the other parties thereto (the "Orphai Acquisition"). The acquisition brought into our pipeline Orphai's lead asset, LAM-001, a proprietary investigational inhaled dry powder formulation of rapamycin whose differentiated characteristics may permit treatment of pulmonary conditions associated with dysfunctional mammalian target of rapamycin activity.

Under the terms of the Merger Agreement, we assumed options to purchase Orphai common stock and were converted into options to purchase an aggregate of 1,308,804 shares of common stock, which options are subject to exercise restrictions prior to obtaining approval during a special meeting of stockholders. In addition, we issued to holders of Orphai warrants (the "Acquisition Warrants") to purchase an aggregate of 10,964.505 shares of Series C Preferred Stock (or 570,169 shares on an as-converted-to-common basis, and without giving effect to any beneficial ownership limitations), at an exercise price of $996.90 per share of Series C Preferred Stock (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split).

On May 18, 2026, concurrent with the Orphai Acquisition, we entered into a securities purchase agreement (the "May 2026 Securities Purchase Agreement") for a private placement financing with new and returning investors to raise up to $187.0 million in gross proceeds, which includes $115.0 million in gross upfront proceeds, net of $11.4 million of offering costs, commissions, legal and other expenses for net proceeds from the offering of $103.6 million and up to an additional approximately $72.0 million upon exercise of accompanying warrants (with an additional up to $11.0 million in gross proceeds available upon the exercise of warrants issued to former Orphai stockholders), in which the investors were issued approximately 144,200.633 shares of our Series C non-voting convertible preferred stock (the "Series C Preferred Stock") (convertible into an aggregate of 7,498,447 shares of common stock, without giving effect to any beneficial ownership limitations) at a price of $797.50 per share and accompanying warrants (the "Financing Warrants") to purchase up to 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at an exercise price of $996.90 per share (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split) (the "May 2026 Financing"). For

additional information on the Orphai Acquisition and the May 2026 Financing, see Note 3 to our unaudited condensed consolidated financial statements.

Following the acquisition, our lead product candidate is LAM-001. We are currently evaluating the use of LAM-001 as a treatment for patients with pulmonary hypertension associated with interstitial lung disease ("PH-ILD") and for patients with bronchiolitis obliterans syndrome post lung transplant ("BOS"), both severe, progressive and often life-threatening indications with few therapeutic alternatives of significant clinical benefit. In our recently completed Phase 2a trial, which enrolled patients with pulmonary arterial hypertension as well as patients with PH-ILD and sarcoidosis associated pulmonary hypertension ("SAPH"), LAM-001 achieved clinically relevant improvement across multiple established endpoints, including pulmonary vascular resistance, six-minute walking distance and functional class. A Phase 2b trial of LAM-001 is ongoing, evaluating 75 patients with PH-ILD, with data expected in the first quarter of 2028. A fully enrolled Phase 2 trial of LAM-001 in BOS is currently ongoing, with results anticipated in the first quarter of 2027. In addition, we expect to initiate a Phase 2 trial to evaluate the use of LAM-001 as a treatment for sarcoidosis-associated pulmonary hypertension in late 2026, with data expected in the fourth quarter of 2028.

Prior to the Orphai Acquisition, our business was focused on developing our proprietary Autologous Intracellular Drug Encapsulation ("AIDE") technology for the treatment of Ataxia-Telangiectasia ("A-T") through our encapsulated dexamethasone sodium phosphate encapsulated in patient's own red blood cells ("eDSP") product candidate. In January 2026, we completed our pivotal Phase 3 NEAT clinical trial of eDSP for the treatment of A-T. As previously disclosed, the primary endpoints of the NEAT trial did not reach statistical significance. Based on the results of the NEAT trial, we determined that we would no longer continue development of eDSP in this or other therapeutic indications, and we are currently considering next steps for the eDSP program and our other assets.

Financial Overview

We have incurred net losses from operations since our inception. As of June 30, 2026, we had an accumulated deficit of $500.0 million. While we generated a net income in the three months ended March 31, 2026, we do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and potentially seek marketing approval for, our product candidates. In addition, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses.

Components of Results of Operations

Operating Expenses

Our operating expenses since inception have consisted primarily of R&D activities and G&A costs.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the research and development of our research programs. These expenses include payroll and personnel expenses, including stock-based compensation, for our research and product development employees, laboratory supplies, product licenses, consulting costs, contract research, regulatory, quality assurance, preclinical and clinical expenses, allocated rent, facilities costs and depreciation. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments and deposits for services that would be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as an expense as the related services are performed.

We anticipate that our research and development expenses will increase from current levels due to the Orphai Acquisition and the increase in headcount as the size of our business and research and development operations grows to support additional research and development activities.

General and Administrative

General and administrative expenses consist principally of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, insurance and accounting services, allocated rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase from current levels due to the Orphai Acquisition and the increase in headcount as the size of our business and research and development operations grows to support additional research and development activities.

Acquired in-process research and development

Acquired in-process research and development expense consists of the fair value of in-process research and development ("IPR&D") acquired in connection with the Orphai Acquisition. As the acquired in-process research and development was determined to have no alternative future use, it was expensed on the acquisition date, in accordance with ASC 730. We do not expect to recognize acquired in-process research and development expense in future periods unless we complete additional acquisitions.

Gain on Orphai Acquisition

Gain on Orphai Acquisition represents the excess of the fair value of the net assets acquired, including IPR&D acquired, and net liabilities assumed in connection with the Orphai Acquisition over the fair value of consideration transferred, recognized as of the acquisition date.

Intangible Asset Impairment Charge

Finite-lived intangible asset consists primarily of the tradename and is amortized on a straight-line basis over their estimated useful lives. Indefinite lived intangible assets are not amortized. Intangible assets related to IPR&D acquired in a business combination or an acquisition that are used in IPR&D shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If the carrying value of the assets is not expected to be recovered, the assets are written down to their estimated fair values. As a result of the clinical readout of the Phase 3 NEAT study in January 2026, which led us to discontinue development of eDSP, several of the assumptions used in determining the initial fair value changed including expected cash flows and thus triggered the need for an interim impairment assessment. As a result, the fair value was determined to be significantly below its carrying value and we recognized a total impairment charge of $67.8 million for for indefinite and finite-lived intangible assets during the six months ended June 30, 2026.

Fair Value Adjustment for Contingent Consideration

We record fair value adjustment for contingent consideration primarily due to the expected timing of achieving various milestones, and the passage of time related to the contingent consideration earnout resulting from the acquisition of EryDel on October 20, 2023 (the "EryDel Acquisition"). Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. As a result of the clinical readout of the Phase 3 NEAT study in January 2026, which led us to discontinue development of eDSP, the criteria for the contingent consideration payments will not be met, resulting in the related liability being reduced to zero.

Fair Value Adjustment for Debt

We record fair value adjustment for debt primarily due to the passage of time and the interest accrued for the loan with the European Investment Bank ("EIB"). In March 2026, the EIB agreed to a full settlement of all obligations associated with the loan with a single payment of 4.8 million euros ($5.5 million) which was paid on March 30, 2026.

Fair Value Adjustment for Warrants

We record fair value adjustment for warrant liability calculated using the Black-Scholes option pricing model, adjustments are due to changes in our stock price, the expected term, volatility, risk-free interest rate, and expected dividends.

Warrant Issuance Costs

Warrant issuance costs consist of expenses incurred in connection with the Financing Warrants, which are classified as liabilities.

Interest Income

Interest income consists primarily of interest earned on our short-term investments portfolio.

Other Income (Expense), net

Other income (expense), net consists primarily of the effects of foreign currency exchange rates.

Critical Accounting Estimates

For a description of our significant accounting policies, see Note 2 to our unaudited condensed consolidated financial statements.

Of our policies, the following are considered critical to an understanding of our condensed consolidated financial statements as they require the application of subjective and complex judgment, involving critical accounting estimates and assumptions impacting our condensed consolidated financial statements:

- Research and Development Expenses
- Impairment of Intangible Assets
- Contingent Consideration
- Debt
- Warrant Liability
- Income Taxes
- Business Combination

For a discussion about the other critical accounting estimates and assumptions impacting our condensed consolidated financial statements, see the *Critical Accounting Estimates* section within MD&A of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on April 10, 2026.

Results of Operations

Comparison of the three months ended June 30, 2026 to the three months ended June 30, 2025

The following sets forth our results of operations for the three months ended June 30, 2026 and 2025 (in thousands, except for percentages):

	For the Three Months Ended June 30,		Change	
	2026	2025	$	%
Operating expenses:				
Research and development	$ 5,461	$ 6,553	$ (1,092)	(17)%
General and administrative	16,626	3,342	13,284	397%
Acquired in-process research and development	59,000	—	59,000	
Gain on Orphai Acquisition	(1,305)	—	(1,305)	
Fair value adjustment for contingent consideration	—	532	(532)	(100)%
Total operating expenses	79,782	10,427	69,355	665%
Loss from operations	(79,782)	(10,427)	(69,355)	665%
Fair value adjustment for debt	—	(501)	501	(100)%
Fair value adjustment for warrants	4,507	(4,464)	8,971	(201)%
Warrant issuance costs	(874)	(872)	(2)	0%
Interest income	584	311	273	88%
Other expense, net	152	(29)	181	(624)%
Net loss before income tax expense	(75,413)	(15,982)	(59,431)	372%
Income tax benefit (expense)	(75)	(67)	(8)	12%
Net loss	$ (75,488)	$ (16,049)	$ (59,439)	370%

Research and Development Expenses *(in thousands, except for percentages):*

	Three Months Ended June 30,		Change	
	2026	2025	$	%
Direct research and development expenses:				
eDSP	$ (736)	$ 4,641	$ (5,377)	(116)%
LAM-001	831	—	831	
Other direct research costs	(16)	102	(118)	(116)%
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	5,287	1,731	3,556	205%
Facilities and other research and development expenses	95	79	16	20%
Total research and development expenses	$ 5,461	$ 6,553	$ (1,092)	(17)%

Research and development expenses were $5.5 million for the three months ended June 30, 2026, compared to $6.6 million for the three months ended June 30, 2025, a decrease of $1.1 million.

The costs for eDSP development decreased by $5.4 million compared to the same period from the prior year due to the ramping down related to our Phase 3 NEAT clinical trial and Open-Label Extension Clinical Trial ("OLE") as well as a gain on the settlement of accounts payable. This decrease was primarily due to a gain on settlement of accounts payable of $1.1 million, as well as a decrease in clinical trial costs of $3.5 million, a decrease in eDSP consulting of $1.1 million, and a decrease in manufacturing costs of $0.2 million, offset by an increase of R&D expenses of $0.5 million related to the reserve and adjustment for R&D tax credits.

The costs for LAM-001 development increased by $0.8 million during the three months ended June 30, 2026 as compared to the three months ended June 30, 2025, due to the Orphai Acquisition as a result of the start-up costs of LAM-001.

Our personnel related costs increased by $3.6 million during the three months ended June 30, 2026 as compared to the three months ended June 30, 2025, mainly as a result of an increase of $2.7 million in allocated stock-based compensation costs and a $0.9 million increase in other personnel related expenses, including costs related to Orphai Acquisition and severance costs related to personnel separation.

General and Administrative Expenses

General and administrative expenses increased by $13.3 million to $16.6 million for the three months ended June 30, 2026, from $3.3 million for the three months ended June 30, 2025. The increase in general and administrative expenses was primarily due to $9.1 million in allocated stock-based compensation and personnel related expenses primarily due to the assumptions of the Orphai historical options upon acquisition, an increase of $4.4 million in consulting and professional costs related to activities related to restructuring and the Orphai Acquisition, offset by $0.2 million related to other professional and administrative costs.

Fair Value Adjustment for Contingent Consideration

For the three months ended June 30, 2026, the fair value adjustment for contingent consideration decreased by $0.5 million as we recorded a fair value adjustment for contingent consideration as a result of the clinical readout of the Phase 3 NEAT study in January 2026.

Fair Value Adjustment for Debt

For the three months ended June 30, 2026, the fair value adjustment for the debt decreased by $0.5 million primarily due to the settlement of the loan with the EIB in March 2026.

Fair Value Adjustment for Warrants

For the three months ended June 30, 2026, we recorded an increase of $9.0 million fair value adjustment for warrants primarily due to the issuance of the Acquisition and Financing Warrants, exercise of the Pre-Funded Warrants, cancellation of the Common warrants, and changes in the price of the underlying stock.

Interest Income

Interest income increased by $0.3 million for the three months ended June 30, 2026, as compared to the three months ended June 30, 2025. The change was due to increased yields on our investment portfolio and increased average balances.

Other Expense, net

Other income (expense), net increased by $0.2 million for the three months ended June 30, 2026 primarily due to unrealized gains from foreign currency translation.

Income Tax Expense

We recorded a tax expense of $75 thousand and $67 thousand for the three months ended June 30, 2026 and 2025, respectively. The tax expense was primarily due to the current-period Italian income tax expense.

Comparison of the six months ended June 30, 2026 to the six months ended June 30, 2025

The following sets forth our results of operations for the six months ended June 30, 2026 and 2025 (in thousands, except for percentages):

	For the Six Months Ended June 30,		Change	
	2026	2025	$	%
Operating expenses:				
Research and development	$ 12,306	$ 14,698	$ (2,392)	(16)%
General and administrative	20,893	8,131	12,762	157%
Acquired in-process research and development	59,000	—	59,000	
Gain on Orphai Acquisition	(1,305)	—	(1,305)	
Intangible asset impairment charge	67,808	—	67,808	
Fair value adjustment for contingent consideration	(64,330)	2,456	(66,786)	(2719)%
Total operating expenses	94,372	25,285	69,087	273%
Loss from operations	(94,372)	(25,285)	(69,087)	273%
Fair value adjustment for debt	12,168	(945)	13,113	(1388)%
Fair value adjustment for warrants	35,623	(4,464)	40,087	(898)%
Warrant issuance costs	(874)	(872)	(2)	0%
Interest income	744	717	27	4%
Other income (expense), net	1,871	(116)	1,987	(1713)%
Net loss before income tax expense	(44,840)	(30,965)	(13,875)	45%
Income tax benefit (expense)	5,264	(114)	5,378	(4718)%
Net loss	$ (39,576)	$ (31,079)	$ (8,497)	27%

Research and Development Expenses *(in thousands, except for percentages):*

	Six Months Ended June 30,		Change	
	2026	2025	$	%
Direct research and development expenses:				
eDSP	$ 2,933	$ 10,868	$ (7,935)	(73)%
LAM-001	831	—	831	
Other direct research costs	649	179	470	263%
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	7,743	3,487	4,256	122%
Facilities and other research and development expenses	150	164	(14)	(9)%
Total research and development expenses	$ 12,306	$ 14,698	$ (2,392)	(16)%

Research and development expenses were $12.3 million for the six months ended June 30, 2026, compared to $14.7 million for the six months ended June 30, 2025, a decrease of $2.4 million.

The costs for eDSP development decreased by $7.9 million compared to the same period from the prior year due to the ramping down related to our Phase 3 NEAT clinical trial and OLE as well as a gain on the settlement of accounts payable. This decrease was primarily due to a gain on settlement of accounts payable of $3.7 million as well as a decrease in clinical trial costs of $5.3 million, a decrease in eDSP consulting of $1.5 million, and a decrease in manufacturing costs of $0.6 million, offset by an increase of R&D expenses of $3.2 million related to the reserve and adjustment for R&D tax credits.

The costs for LAM-001 development increased by $0.8 million during the six months ended June 30, 2026 as compared to the six months ended June 30, 2025, due to the Orphai Acquisition as a result of the start-up costs of LAM-001.

Personnel related costs increased by $4.3 million during the six months ended June 30, 2026 as compared to the six months ended June 30, 2025, mainly as a result of an increase of $2.9 million in allocated stock-based compensation costs and a $1.4 million increase in other personnel related expenses, including costs related to Orphai Acquisition and severance costs related to personnel separation.

General and Administrative Expenses

General and administrative expenses increased by $12.8 million to $20.9 million for the six months ended June 30, 2026, from $8.1 million for the six months ended June 30, 2025. The increase in general and administrative expenses was primarily due to $8.5 million in allocated stock-based compensation and personnel related expenses primarily due to the assumptions of the Orphai historical options upon acquisition, and an increase of $4.3 million in consulting and professional costs related to the restructuring activities.

Intangible Asset Impairment Charge

During the six months ended June 30, 2026, we conducted an impairment analysis of our intangible asset IPR&D and tradename that resulted from the EryDel Acquisition in October 2023. We conducted a quantitative analysis which resulted in our fair value being significantly below our current carrying value due to the assumptions changing as a result of the Phase 3 NEAT study in January 2026. As a result of the analyses, we recorded a non-cash intangible asset impairment charge of $67.8 million for the six months ended June 30, 2026.

Fair Value Adjustment for Contingent Consideration

For the six months ended June 30, 2026, we recorded a $64.3 million fair value adjustment for contingent consideration as a result of the clinical readout of the Phase 3 NEAT study in January 2026.

Fair Value Adjustment for Debt

For the six months ended June 30, 2026, we recorded a $12.2 million fair value adjustment for the debt primarily due to the settlement of the loan with the EIB in March 2026.

Fair Value Adjustment for Warrants

For the six months ended June 30, 2026, we recorded an increase of $40.1 million in fair value adjustment for warrants primarily due to timing of issuance of the Acquisition and Financing Warrants and change in the price of our common stock.

Interest Income

Interest income increased by $27 thousand for the six months ended June 30, 2026, as compared to the six months ended June 30, 2025. The change was due to increased yields on our investment portfolio and increased average balances.

Other Income (Expense), net

Other income (expense), net increased by $2.0 million for the six months ended June 30, 2026, primarily due to unrealized gains from foreign currency translation.

Income Tax Benefit (Expense)

We recorded $5.3 million of tax benefit for the six months ended June 30, 2026 and tax expense of $0.1 million for the six months ended June 30, 2025. The tax benefit was primarily related to discrete release of uncertain tax position liabilities associated with certain intellectual property following changes in facts and circumstances in the six months ended June 30, 2026 that affected the valuation of the intellectual property.

Liquidity and Capital Resources

We have not generated any revenue and we have never been profitable. To date, we have financed our operations primarily through the issuance and sale of our securities. From inception through June 30, 2026, we received net proceeds of approximately $345.7 million from the issuance of redeemable convertible preferred stock, convertible promissory notes, common warrants, pre-funded warrants, and common stock.

We have incurred net losses from operations since our inception. As of June 30, 2026, we had an accumulated deficit of $500.0 million. While we generated a net income in the three months ended March 31, 2026, we do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and potentially seek marketing approval for, our product candidates. In addition, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for our current and future product candidates;
- the cost and timing of the manufacture of additional clinical trial material as well as any costs related to the scale-up of manufacturing activities;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the need to hire additional clinical, quality assurance, quality control and other scientific personnel;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the terms of any collaboration agreements we may choose to enter into, including the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the cost associated with the expansion of our operational, financial and management systems and increased personnel, including personnel to support our operations as a public company; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize.

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that our unaudited condensed consolidated financial statements are issued.

Concurrent with the Orphai Acquisition, in May 2026, we completed the May 2026 Financing, providing $115.0 million in upfront proceeds, with the potential to receive up to an additional $72.0 million in gross proceeds upon the exercise of the Financing Warrants (with an additional up to $11.0 million in gross proceeds available upon the exercise of warrants issued to former Orphai stockholders). The Series C Preferred Stock is subject to automatic conversion into common stock upon the third business day following our receipt of stockholder approval in accordance with Nasdaq Listing Rules, subject to certain beneficial ownership limitations. The Certificate of Designation of Preferences, Rights and Limitations of the Series C Non-Voting Convertible Preferred Stock (the “Certificate of Designation”) provides that, at any time following the earlier of (i) stockholder approval or (ii) six months after the initial issuance of the Series C Preferred Stock, if we fail to timely deliver shares of common stock to a converting holder in accordance with the terms of the Certificate of Designation, such holder may require us to pay cash in an amount equal to the fair value of the undelivered shares. As a result, we concluded that the proceeds received from the May 2026 Financing cannot be relied upon to mitigate conditions that raise substantial doubt because the availability of those proceeds is subject to conditions that are not

entirely within our control. The conversion of the Series C Preferred Stock into common stock and therefore removal of the requirement to make cash payment based on the value of the undelivered shares is subject to the vote of our stockholders.

Our ability to satisfy these potential cash settlement obligations associated with the Series C Preferred Stock is not entirely within our control, as it is contingent on, among other things, our ability to obtain stockholder approval and to deliver shares of common stock upon conversion within the timeframes required by the Certificate of Designation. If we are unable to obtain stockholder approval in a timely manner, or are otherwise unable to timely deliver shares of common stock upon conversion, holders who submit conversion notices after the applicable trigger date could require us to make significant cash payments that could substantially reduce our available cash resources. Factoring in these potential cash payments, based on our current operating plan, we believe that our cash and cash equivalents balance will not be sufficient to fund operations and capital expenditures for at least the twelve months following the issuance of our unaudited condensed consolidated financial statements. Accordingly, we concluded that substantial doubt about our ability to continue as a going concern continues to exist within one year after the date our financial statements are available to be issued.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Our cash, cash equivalents, and marketable debt securities are held in a variety of deposit accounts, interest-bearing accounts, U.S government securities, debt securities in government-sponsored entities, and money market funds. Cash in excess of immediate requirements, if any, is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and credit risk. Our cash equivalents and short-term investments are held in money market funds and government agency obligations.

Until such time, if ever, as we can generate product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Financing

Equity Financing

ATM Program

On December 18, 2024, we entered into a Controlled Equity Offering[SM] Sales Agreement, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the "Agents"), relating to the sale of shares of our common stock. In accordance with the terms of this agreement, we could offer and sell up to $21.9 million of shares of common stock. In October 2025, we increased the total amount available under the ATM program to $75.0 million.

During the three and six months ended June 30, 2026, we utilized our ATM program to raise net proceeds of approximately $5.4 million and $20.3 million by issuing 125,500 shares and 526,435 shares of common stock, respectively. As of June 30, 2026, $47.5 million remained available to be sold under the ATM program.

May 2026 Private Placement

On May 18, 2026, concurrent with the Orphai Acquisition, we entered into the May 2026 Securities Purchase Agreement for a private placement financing with new and returning investors to raise up to $187.0 million in gross proceeds, which includes $115.0 million in upfront proceeds and up to an additional approximately $72.0 million upon exercise of the Financing Warrants, in which the investors were issued approximately 144,200.633 shares of Series C Preferred Stock (convertible into an aggregate of 7,498,447 shares of common stock, without giving effect to any beneficial ownership limitations) at a price of $797.50 per share and Financing Warrants to purchase up to 72,100.322 shares of Series C Preferred Stock (or 3,749,231 shares, on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at an exercise price of $996.90 per share (or $19.17 per share on an as-converted-to-common basis, as adjusted for the June 2026 Reverse Stock Split). For additional information on the May 2026 Financing, see Note 10 to our unaudited condensed consolidated financial statements.

June 2025 Private Placement

On June 12, 2025, we entered into a Securities Purchase Agreement (the “June 2025 Securities Purchase Agreement”), with certain institutional investors (the “Investors”) and certain members of our management (together with the Investors, the “Purchasers”) pursuant to which we issued and sold to the Purchasers in a private placement (the “Private Placement”): (i) 33,360 shares (the “Shares”) of our common stock, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to an aggregate of 10,000 shares of common stock, and (iii) accompanying warrants to purchase up to an aggregate of 43,360 shares of common stock (the “Common Warrants”), for aggregate gross proceeds of approximately $11.5 million (excluding up to approximately $10.4 million of aggregate gross proceeds that may be received in the future upon the cash exercise in full of the Common Warrants issued in the Private Placement), before deducting placement agent fees and other expenses payable by us. Each Share and each Pre-Funded Warrant sold pursuant to the Securities Purchase Agreement was accompanied by one Common Warrant. The combined purchase price of each Share and accompanying Common Warrant was $265.00 (which included $25.00 per Common Warrant in accordance with the rules and regulations of Nasdaq). The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrant was $264.80 (equal to the combined purchase price per Share and accompanying Common Warrant, minus $0.20).

Debt

In connection with the acquisition of EryDel on October 20, 2023, we guaranteed the EIB Loan. The EIB Loan was amended and restated as of the acquisition date. The EIB Loan provided for maximum borrowings of 30.0 million euro through four tranches; tranche A, 3.0 million euro; tranche B, 7.0 million euro; tranche C, 10.0 million euro; and tranche D, 10.0 million euro. Each tranche was subject to conditions precedent related to our business and capitalization. Only tranches A and B were drawn. All amounts under tranche A and B were payable on their maturity date of August 2026. Interest accrued at fixed rates for each tranche and both principal and interest was payable on the maturity date for each tranche (with the exception of 2% cash interest which was accrued and payable

quarterly during fiscal year 2025 pursuant to the terms of the Amendment (as defined below), which correspondingly reduced the deferred interest rate accruing during such period). The fixed rates ranged from 7.0% to 9.0% per annum.

On March 27, 2026, we entered into a loan settlement agreement (the "Settlement Agreement") with the EIB in connection with the EIB loan. Pursuant to the Settlement Agreement, effective immediately upon our payment of 4.8 million euros ($5.5 million), our outstanding obligations to the EIB were settled in full and all of our obligations were satisfied and discharged.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	For the Six Months Ended June 30,		
	2026	2025	Change
Net cash (used in) provided by:			
Operating activities	$ (26,514)	$ (21,016)	$ (5,498)
Investing activities	20,001	16,937	3,064
Financing activities	118,376	14,499	103,877
Effect of exchange rate changes on cash	(1,691)	194	(1,885)
Net increase in cash and cash equivalents	$ 110,172	$ 10,614	$ 99,558

Operating Activities

Net cash used in operating activities decreased by $5.5 million during the six months ended June 30, 2026 compared to the six months ended June 30, 2025, primarily due to lower operating payments driven by decreased clinical development activities. Net cash used in operating activities was $26.5 million for the six months ended June 30, 2026. Cash used in operating activities was primarily due to our net loss of $39.6 million for the period, adjusted for $23.0 million of non-cash items, including $67.8 million non-cash impairment on intangible assets, $64.3 million change in the fair value of contingent consideration liabilities, $59.0 million acquired in-process research and development from the Orphai Acquisition, $35.6 million change in the fair value of warrants, $13.4 million in stock-based compensation, $12.2 million change in the fair value of the EIB Loan, $3.7 million in gain on settlement of accounts payable, and a net increase in our operating assets of $1.1 million and a net increase in our accounts payable, and accrued expenses and other current liabilities of $8.9 million.

Investing Activities

Cash provided by investing activities was $20.0 million for the six months ended June 30, 2026, primarily related to the proceeds from maturities of short-term investments of $12.0 million and the net cash assumed in the Orphai Acquisition of $8.0 million.

Cash provided by investing activities was $16.9 million for the six months ended June 30, 2025, primarily related to the maturities of short-term investments of $31.0 million, and the purchase of investments of $13.8 million.

Financing Activities

Cash provided by financing activities was $118.4 million for the six months ended June 30, 2026, which consisted of $103.6 million of proceeds from the issuance of Series C Preferred Stock and Financing Warrants pursuant to the May 2026 Private Placement, $20.3 million from the issuance of common stock in connection with the ATM offerings, offset by the repayment of debt of $5.5 million.

Cash used in financing activities was $14.5 million for the six months ended June 30, 2025, which consisted of gross proceeds of $11.5 million from the issuance of common stock, common warrants, and pre-funded warrants in connection with June 2025 Private Placement, $2.9 million from the issuance of common stock in connection with the ATM offerings, and $0.2 million from the exercise of stock options in the period.

Contractual Obligations and Commitments

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations.

We enter into contracts in the normal course of business with third party contract organizations for clinical trials, non-clinical studies and testing, manufacturing, and other services and products for operating purposes. The amount and timing of the payments under these contracts varies based upon the timing of the services. We have recorded accrued expense of approximately $3.9 million in our condensed consolidated balance sheets for expenditures incurred by these vendors as of June 30, 2026. Our cancellable future operating expense commitments based on existing contracts as of June 30, 2026 is $2.5 million. These obligations will be satisfied in the normal course of business, but generally no longer than 12 months. In March 2026, we entered into a Settlement Agreement with the EIB to settle our outstanding obligations in full with a single payment of 4.8 million euros ($5.5 million). Following such payment, all of our obligations to the EIB were satisfied and discharged. Additionally, in March 2026, it was determined that the criteria for the contingent consideration payouts will not be met, resulting in the related liability being reduced to zero. As of June 30, 2026, the fair value of warrants issued in connection with the June 2025 and May 2026 private placements is $6.3 million.

In addition, our future capital requirements will depend on, among other things, the timing of stockholder approval of the Company Stockholders Matters (as defined in the Merger Agreement as the "Parent Stockholder Matters") and the potential cash settlement obligations that may arise if we are unable to timely deliver shares of our common stock upon conversion of the Series C Preferred Stock issued in connection with the Orphai Acquisition and the May 2026 Financing. The Series C Preferred Stock is subject to automatic conversion into common stock upon the third business day following our receipt of stockholder approval in accordance with Nasdaq Listing Rules, subject to certain beneficial ownership limitations. The Certificate of Designation of Preferences, Rights and Limitations of the Series C Non-Voting Convertible Preferred Stock (the "Certificate of Designation") provides that, at any time following the earlier of (i) stockholder approval or (ii) six months after the initial issuance of the Series C Preferred Stock, if we fail to timely deliver shares of common stock to a converting holder in accordance with the terms of the Certificate of Designation, such holder may require us to pay cash in an amount equal to the fair value of the undelivered shares.

Our ability to satisfy these potential cash settlement obligations is not entirely within our control, as it is contingent on, among other things, our ability to obtain stockholder approval and to deliver shares of common stock upon conversion within the timeframes required by the Certificate of Designation. If we are unable to obtain stockholder approval in a timely manner, or are otherwise unable to timely deliver shares of common stock upon conversion, holders who submit conversion notices after the applicable trigger date could require us to make significant cash payments that could substantially reduce our available cash resources.

Additionally, even following stockholder approval, certain holders may be unable to convert their Series C Preferred Stock due to the application of beneficial ownership limitations. Shares of Series C Preferred Stock that are not converted in the automatic conversion on account of beneficial ownership limitations will remain outstanding until converted at the option of the applicable holders, and the cash settlement provisions described above would apply to any failure to timely deliver conversion shares in connection with any such optional conversion.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms. Any disclosure controls and

procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including the Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2026. Based on that evaluation, the Chief Executive Officer and Principal Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

Except as set forth below, there have been no changes in our internal control over financial reporting during the quarter ended June 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

On May 18, 2026, we completed our acquisition of Orphai, as further described in Note 3 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. In connection with the acquisition, we have begun the process of integrating Orphai's financial processes, systems, and personnel into our system of internal control over financial reporting during the three months ended June 30, 2026. We expect this integration to continue through the remainder of 2026 and to result in changes to 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 business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 1A. Risk Factors.

In addition to the other information set forth below and elsewhere in this report, you should carefully consider the risks described below, as well as general economic and business risks and the other information herein. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- We need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to further delay, limit, reduce or terminate our product development or commercialization efforts.
- We have incurred significant losses every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the success of LAM-001. LAM-001 will require additional clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.
- If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available.
- We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

- We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.
- If the FDA does not conclude that LAM-001 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for LAM-001 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and may not be successful.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The success of our product candidates will depend on several factors, including obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for our product candidates.
- If we are unable to obtain and maintain patent protection for our technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.
- There is no guarantee that the Acquisition will increase stockholder value.
- Pursuant to the terms of the Acquisition and related 2026 Private Placement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series C Preferred Stock into shares of our common stock. We must also obtain stockholder approval of an amendment to our certificate of incorporation to increase the number of shares we are authorized to issue. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations would be materially harmed.
- Our failure or perceived failure to comply with data privacy and security obligations including our experiencing security incidents could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase our costs and otherwise negatively affect our operating results and business.
- The failure to successfully integrate the businesses of Quince and Orphai in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have a history of significant losses since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess the future viability of our business prospects. Our operations to date have been limited to business planning, including the Acquisition, organizing and staffing our company, raising capital, identifying potential product candidates, conducting clinical trials and preclinical studies for our development programs, entering into licensing agreements, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations.

We have a history of significant net losses since our inception. Our net loss was $39.6 million and $31.1 million for six months ended June 30, 2026 and 2025, respectively, and $84.0 million and $56.8 million for the years ended December 31, 2025 and 2024, respectively. As of June 30, 2026 and as of December 31, 2025, we had an accumulated deficit of $500.0 million and $460.5 million, respectively. We have funded our operations to date primarily with proceeds from the sale of our equity securities and borrowings of convertible debt.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of LAM-001. Investment in clinical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we 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 would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty, particularly with respect to the Acquisition. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, we have used substantial amounts of capital to fund the development of our product candidates and operations. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as our product candidates enter and advance through preclinical studies and clinical trials. We will require substantial additional funding to meet our financial needs and to pursue our business objectives. We will require significant additional capital to, among other things:

- complete our ongoing and planned clinical trials, preclinical studies and IND-enabling activities;
- initiate, enroll, and complete additional clinical trials for our product candidates;
- seek and obtain regulatory approvals for our product candidates;

- build and maintain our manufacturing capabilities or enter into third-party manufacturing arrangements;
- expand and protect our intellectual property portfolio; and
- fund our general and administrative operations.

In addition, if we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses related to marketing, sales, administration and manufacturing and distribution.

Failure to raise capital as and when needed would have a negative impact on our financial condition and ability to develop our product candidates. Furthermore, we cannot be certain that additional funding will be available on acceptable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives, and any of our current or future license agreements may be terminated if we are unable to meet the payment or other obligations under the agreements.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales are likely to result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

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, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, geopolitical conflicts, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

Fluctuating interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets.

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with acquisitions. For example, during the quarter ended June 30, 2024, we incurred a $17.1 million goodwill impairment charge in connection with the EryDel Acquisition. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we assumed as a result of the EryDel Acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition. We recognized a total impairment charge of $67.8 million for indefinite and finite-lived intangible assets for the six months ended June 30, 2026 related to the negative outcome of the NEAT study.

Our failure to maintain certain tax benefits applicable to Italian biotechnology companies may adversely affect our results of operations, our cash flows and our financial condition.

We have benefited from certain tax advantages related to our Italian biotechnology subsidiary, including, for example, the R&D tax credit, which is an Italian tax credit aimed at stimulating research and development. The R&D tax credit can offset payments of certain taxes and contributions (e.g., social contributions, VAT payables, registration fees, income and withholding taxes and all other tax-related items that companies usually pay monthly). For eligible research and development activities, the tax credits were equal to 20% of the costs incurred in fiscal years 2022 and 2021, with a maximum annual amount of $4.4 million (4 million euros). In 2023 the general R&D tax credit rate was decreased to 10% of the eligible expenses for certain activities, and the annual ceiling of the credit increased to $5.5 million (5 million euros). In 2023 to 2025, we generated R&D tax credit under Article 31 of Decree-Law No. 73/2021, for Pharmaceutical/Vaccine R&D tax credit, which has tax credits equal to 20% of cost incurred in the fiscal year and annual ceiling of the credit of $23.4 million (20 million euros). Expenses incurred for years ended December 31, 2025, 2024, and 2023 generated a total tax credit amounting to $1.9 million (1.7 million euros), $1.7 million (1.6 million euros), and $0.9 million (0.8 million euros), respectively. The Italian tax authorities may audit each research and development program in respect of which a R&D tax credit has been claimed and assess whether such program qualifies in its view for the R&D tax credit. The Italian tax authorities may challenge

our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities. Should the Italian tax authorities be successful, the R&D tax credit, may be reduced, which would have a negative impact on our results of operations and future cash flows. We believe, due to the nature of our business operations, that we will continue to be eligible to receive the R&D tax credit. However, if the Italian government decides to eliminate, or to reduce the scope or the rate of, the R&D tax credit, either of which it could decide to do at any time, our results of operations could be adversely affected.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. If we are unable to advance LAM-001 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that any clinical trials of LAM-001, or any other product candidates we may develop will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any such product candidate. LAM-001 is in the early stage of our development efforts, and if it, or any product candidate that we may develop, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. We initiated a Phase 2b clinical trial of LAM-001 in PH-ILD in July 2026. Additionally, an investigator-initiated Phase 2 clinical trial of LAM-001 in BOS is being conducted, and we expect to initiate a Phase 2 clinical trial of LAM-001 in SAPH in late 2026.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- initiating, enrolling, and completing clinical trials;
- submission of INDs for and receipt of allowance to proceed with our clinical trials or other future clinical trials;
- completing preclinical studies;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- manufacturing our product candidates at an acceptable cost and quality; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which could materially harm our business.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for LAM-001 or any other product candidate we may develop, our business will be substantially harmed.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain and maintain regulatory approval for our development products, in particular LAM-001. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate to ensure sufficient product quality and control with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials, the type and amount of clinical data necessary, the Chemistry, Manufacturing and Controls, or CMC, requirements to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial 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. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes, or failure to obtain such approvals with respect to our facilities or the facilities of our contract manufacturing vendors;
- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval;
- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;
- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;
- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy current good manufacturing practice, or cGMP, requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;
- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize our product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, controls, specifications, labeling, instructions or packaging, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. Further, if we change the primary or secondary endpoints in any of our clinical trials, either by our own choice or at the request of the FDA or a comparable regulatory authority, our development plans could be delayed, our costs could increase and our business could be materially harmed. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product candidate or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of LAM-001. LAM-001 will require additional clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting substantially all our resources to the development of LAM-001 across our three target indications of PH-ILD, BOS (in post-lung transplant patients) and SAPH. Our existing clinical data for LAM-001 in PH-ILD is derived from a completed, open-label Phase 2a clinical trial with a limited number of evaluable patients. In addition, an investigator-initiated double-blind Phase 2 clinical trial in BOS and a company-sponsored double-blind Phase 2b trial in PH-ILD are ongoing, each with a limited number of evaluable patients. If LAM-001, across the various target indications, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Because substantially all of our resources are concentrated on a single product candidate, any failure or significant delay in LAM-001's development would have a disproportionate impact on our business, financial condition and prospects, and we do not have other clinical-stage programs that could offset such a setback.

We cannot provide you with any assurance that we will be able to successfully advance LAM-001 or any additional product candidates through the development process in any particular target indication. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which could have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, of sufficient purity and effective for use in each target indication, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. A failure of one or more clinical trials can occur at any stage of testing. Any side effects or patient deaths could affect the development of our product candidates, even if deemed to not be drug related.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities, or the facilities of our contract manufacturing vendors;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval
- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;
- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;
- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy current good manufacturing practice, or cGMP, requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;
- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdictions to approve our NDAs or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Human clinical trials are expensive, can take many years to complete, and are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for serious pulmonary disorder product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Negative outcomes or data integrity failures by competitors in the serious pulmonary disorder space could adversely affect our business, reputation, and the regulatory and commercial environment in which we operate.

The clinical and commercial success of LAM-001 may be influenced not only by our own data and results, but also by the outcomes and perceived integrity of data generated by competitors operating in the same therapeutic area. If a competitor's product or product candidate is withdrawn from the market, subject to a safety recall, or associated with serious adverse events, whether in clinical trials or following regulatory approval, patients, physicians, payers, and the broader medical community may develop a generalized skepticism or loss of confidence in the underlying treatment modality or target mechanism. This loss of confidence could reduce patient enrollment in our clinical trials, dampen physician adoption of our products, or cause payers to impose more restrictive coverage and reimbursement policies, regardless of whether our products share the specific deficiencies identified in the competitor's product.

We have no control over the research, development, manufacturing, or commercial practices of our competitors in the respiratory disease space, and we cannot predict whether their data or products will meet the standards expected by regulators, the medical community, or the public. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, we are currently focusing the majority of our efforts on the development of LAM-001, and specifically for the clinical indications of PH-ILD, BOS and SAPH. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. We do not know whether our candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in preclinical or clinical development despite positive results observed in early preclinical studies or having successfully advanced through initial clinical trials. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. Further, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these trials may not be indicative of results of future clinical trials.

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

We expect to publish from time to time interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline 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. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.

As a result, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials 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 reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Since the number of patients that have been and will be dosed in our completed and ongoing clinical trials of LAM-001 is small, the results from such clinical trials may be less reliable than or may not be predictive of results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for LAM-001.

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the characteristics of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. Our completed Phase 1 clinical trial of LAM-001 enrolled seven patients in the initial dosing period, with only three patients continuing through an optional 84-day extension period. Our Phase 2a clinical trial in PH, PH-ILD and pulmonary sarcoidosis enrolled ten patients, of whom only six completed the full 24-week trial period. The ongoing Phase 2 clinical trial of LAM-001 in BOS has enrolled 19 patients. The small number of patients enrolled in each of these trials limits the statistical power of our results and increases the potential for any individual patient outcome to disproportionately influence our overall findings. As a result, there may be less certainty that LAM-001 would achieve a statistically significant effect in any future clinical trials.

Of particular note, our clinical thesis for evaluating LAM-001 as a potential treatment for SAPH is supported in part by observations from a single patient with sarcoidosis-associated pulmonary hypertension enrolled in our Phase 2a clinical trial. We intend to initiate a Phase 2 clinical trial specifically to evaluate LAM-001 as a treatment for SAPH; however, there can be no assurance that the results observed in this single patient will be replicated in a broader patient population. In addition, the ongoing Phase 2 clinical trial of LAM-001 for BOS is an investigator-sponsored trial, over which we have limited control with respect to trial conduct, protocol amendments, data access and publication decisions. We may rely in part on the results of this investigator-sponsored trial to inform our future clinical development decisions and allocation of resources for LAM-001 in BOS; however, if those results are not indicative of data that would be generated in a larger, company-sponsored clinical trial, our assumptions in support of our clinical development activities may prove to be inaccurate and the FDA or other comparable regulatory authorities may require us to conduct additional and larger clinical trials than we currently plan.

If we conduct any future clinical trials of LAM-001 or our other product candidates, we may not achieve a positive or statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on prior results from our completed or ongoing trials. Such failure could hinder our efforts to obtain regulatory approval for LAM-001 or our other product candidates.

The comparisons we present regarding LAM-001's safety and efficacy profile relative to oral rapamycin are subject to significant limitations and may not be predictive of LAM-001's relative performance in future controlled studies.

Herein, and in our other public communications, we present data comparing LAM-001's pharmacokinetics, mechanism of action and emerging clinical profile to published data of oral rapamycin. These comparisons are derived from different preclinical studies and clinical trials of both LAM-001 and oral rapamycin conducted at different times, with differences in trial design, patient populations, disease settings, dosing regimens, endpoints, sample sizes, follow-up periods, and adverse event grading criteria. No head-to-head clinical trials have been conducted comparing LAM-001 to rapamycin, and cross-trial comparisons are inherently limited and may not accurately reflect the relative safety or efficacy of the agents being compared.

Physicians, patients, investors, and regulatory authorities may draw conclusions from these cross-trial comparisons that are not supported by the underlying data, or may discount LAM-001's potential based on the inherent limitations of such comparisons. If LAM-001's clinical profile does not compare as favorably to oral rapamycin as our cross-trial analyses suggest, the commercial prospects and perceived differentiation of LAM-001 could be materially diminished.

We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- clinicians' and patients' perceptions as to any risks associated with our competitors' product candidates;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment;
- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical sites available;
- delays in activating clinical trial sites, including delays related to site contracting, budgeting, institutional review board or ethics committee approvals, training or initiation activities;
- high screen failure rates, including as a result of narrow eligibility criteria, required diagnostic confirmation or other protocol-specific requirements;
- competition from approved therapies, standard-of-care alternatives or other treatment options that may reduce patients' willingness to enroll in our clinical trials;

- the burden on patients participating in our clinical trials, including visit frequency, travel requirements, monitoring obligations, procedures, follow-up requirements or other protocol-related demands;
- the availability of specialized testing, biomarkers or diagnostic tools needed to identify or confirm eligible patients;
- our ability to enroll a sufficiently diverse and representative patient populations across demographics, disease characteristics or geographies to support regulatory review;
- patient retention, protocol adherence and timely completion of trial visits and procedures, including missed visits, noncompliance or withdrawal of consent; and
- site staffing constraints, investigator turnover or limited clinical trial infrastructure.

In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our projections of addressable market opportunity for LAM-001 are based on estimates and assumptions that may prove incorrect, and the actual commercial opportunity may be substantially smaller than we expect.

We have made internal estimates of the total addressable market for LAM-001 and other product candidates targeting the mTOR pathway, including estimates of patient populations, treatment penetration rates, and potential pricing. These estimates are based on a variety of sources, including published scientific literature, epidemiological data, market research and our own calculations and assumptions about competitive dynamics. However, these estimates are inherently uncertain and may prove to be materially incorrect.

The actual addressable market for LAM-001 may be smaller than we estimate for several reasons, including: the subset of patients who meet the clinical criteria likely required for treatment with LAM-001 may be smaller than what we project; physicians may not adopt LAM-001 over established therapies; payors may restrict reimbursement; LAM-001 may initially be approved only for later-line treatment settings with smaller patient populations; competing products may capture significant market share before LAM-001 reaches the market; and advances in respiratory disease therapies may further segment the patient population. If the actual market opportunity for LAM-001 is materially smaller than our estimates, we may not be able to generate sufficient revenue to justify our development investment, which could have a material adverse effect on our business and financial condition.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials will include patients suffering from serious pulmonary disorders, mainly PH-ILD, BOS and SAPH, who are very sick and whose health is deteriorating. It is possible that some of these patients may experience side effects during our clinical trials. Further, systemic mTOR inhibitors, including approved rapalogs such as everolimus and temsirolimus, have been associated with numerous adverse events, including opportunistic infections, urinary tract infection, upper respiratory tract infection, nasopharyngitis, pneumonia, pneumocystis carinii pneumonia, pyelonephritis, sepsis, herpes simplex infection, herpes zoster, BK virus-associated nephropathy, progressive multifocal leukoencephalopathy, latent viral infection reactivation, tuberculosis, basal cell carcinoma, squamous cell carcinoma, melanoma, lymphoma, neuroendocrine carcinoma of the skin (Merkel cell carcinoma); hypersensitivity reactions: anaphylactic/anaphylactoid reactions, hypersensitivity vasculitis; hypertension; peripheral edema; angioedema edema; fluid accumulation; ascites; pericardial effusion; tachycardia; venous thromboembolism (including pulmonary embolism, deep venous thrombosis); hemolytic uremic syndrome/thrombotic thrombocytopenic purpura/thrombotic microangiopathy HUS/TTP/TMA; interstitial lung disease (including pneumonitis, bronchiolitis obliterans organizing pneumonia, and pulmonary fibrosis); non-infectious

pneumonitis; bronchial anastomotic dehiscence; increased creatinine; decline in renal function; proteinuria; nephrotic syndrome; focal segmental glomerulosclerosis; hypercholesterolemia: hypertriglyceridemia, hyperlipidemia; diabetes mellitus; increased AST/SGOT; increased ALT/SGPT; hyperglycemia; hypokalemia; anemia; leukopenia; neutropenia; thrombocytopenia; pancytopenia; arthralgia; myalgia; bone necrosis; hepatotoxicity (including fatal hepatic necrosis); hepatic artery thrombosis; lymphocele; lymphedema; posterior reversible encephalopathy syndrome; ovarian cysts; menstrual disorders (including amenorrhea, menorrhagia); azoospermia; increased lactate dehydrogenase; headache; dizziness; fever; pain; abdominal pain; constipation; diarrhea; nausea; stomatitis; acne; rash; exfoliative dermatitis; abnormal/impaired wound healing. While we believe the inhaled route of administration of LAM-001 may reduce systemic exposure relative to orally administered rapamycin, we cannot be certain that toxicity will not occur. This risk may be of particular significance in our target patient populations of patients with PH-ILD, BOS and SAPH whose underlying pulmonary conditions may make them more susceptible to mTOR-associated toxicities. If these or other adverse effects occur with unacceptable frequency or severity in our clinical trials, our ability to develop and commercialize LAM-001 could be materially impaired. Further, patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates, because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, by the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

If the FDA does not conclude that LAM-001 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for LAM-001 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and may not be successful.

We intend to seek FDA approval of LAM-001 through the Section 505(b)(2) regulatory approval pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) allows an NDA we submit to 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 LAM-001 by potentially decreasing the

amount of clinical data that we would need to generate in order to obtain FDA approval. Specifically, we intend to rely on the FDA's prior conclusions regarding the safety and effectiveness of sirolimus (rapamycin), as reflected in the FDA's prior approvals of Rapamune for kidney transplant rejection prevention and lymphangioleiomyomatosis, as well as on published scientific literature regarding the use of rapamycin in pulmonary disease. An applicant seeking approval under the 505(b)(2) pathway must nonetheless submit sufficient data to support approval of its product, including data needed to establish a scientific bridge between the applicant's product and the data or findings on which it seeks to rely, and the type and amount of additional data required depend on the nature of the proposed product and the differences between that product and the reference product or underlying data.

There can be no assurance that the FDA will agree that an adequate scientific bridge has been established between LAM-001 and the approved oral formulations of rapamycin on which we intend to rely. LAM-001 is a novel inhaled dry powder formulation of rapamycin specifically designed to achieve high localized lung concentrations while minimizing systemic exposure, which has a pharmacokinetic profile that differs materially from that of approved oral rapamycin, which achieves therapeutic effect through systemic blood concentrations. The FDA's prior conclusions regarding the safety and effectiveness of rapamycin were made in the context of its systemic administration, and the FDA may determine that those conclusions cannot be meaningfully extended to an inhaled formulation with a distinct pharmacokinetic profile without additional clinical data. The indications we are seeking also differ from the indications for which oral rapamycin is currently approved, which may further limit our ability to rely on the FDA's prior findings and require us to generate more original clinical data than the 505(b)(2) pathway would otherwise necessitate. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or requires us to generate data beyond what we currently plan to generate in order to establish an adequate scientific bridge, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than LAM-001, which would likely materially adversely impact our competitive position and prospects.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDA for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

We are targeting serious pulmonary disorders, which presents additional risks with respect to clinical development, regulatory approvals and commercialization of product candidates.

Our approach of targeting serious pulmonary disorders such as PH-ILD, BOS and SAPH presents risks related to the clinical development, regulatory approval and commercialization of our product candidates, including the following:

- we may have difficulty establishing safety and efficacy in these types of patient populations given the severe and rapidly progressing nature of the diseases we are targeting;
- with respect to BOS and SAPH, the underlying etiologies of the diseases are incompletely understood, which may impact our ability to design adequate and well controlled trials;
- we expect to face challenges with respect to patient enrollment in our clinical trials, as described above;

- small sample sizes in our clinical trials suggest that we face the risk of substantial variability in the results of our trials, and so the outcome of nonclinical testing and early clinical trials is less likely to be predictive of the success of later-stage clinical trials;
- following approval of our product candidates, if any, pricing and level of reimbursement may not be sufficient to offset costs of development, manufacturing, marketing, and commercialization;
- we may have difficulty selecting, validating, and/or achieving clinically meaningful endpoints that are acceptable to regulatory authorities;
- we may have difficulty in accurately diagnosing, stratifying or confirming patients with PH-ILD, BOS or SAPH which could adversely affect enrollment, clinical trial design and interpretation of results;
- regulatory authorities may require larger, longer, additional or different clinical trials than we anticipate, including studies in specific subpopulations or trials designed to address particular safety, efficacy or dosing questions; and
- market size is a significant variable in the disease indications we are targeting.

Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, patient advocacy groups or market research. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may be more difficult to identify and access than our estimates contemplate.

Adverse developments with respect to any of the foregoing could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations, or CROs, or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical 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 information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our 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 candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and

clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

Medical devices necessary for the administration of LAM-001 are subject to regulatory requirements that we must satisfy as part of our NDA and any post-approval obligations.

LAM-001 is administered using a dry powder inhaler, which is manufactured by a third party. LAM-001, if approved, will be regulated by the FDA as a combination product, and our NDA must include data sufficient to demonstrate that the LAM-001 drug-device combination performs safely and as intended for use by our target patient populations. While the inhaler is an established device currently used to deliver multiple approved inhaled therapeutics, we must independently validate the specific drug-device combination as part of our NDA submission. Regulatory authorities may require user-factor studies as a part of our NDA submission.

The FDA will require human factors and usability testing to demonstrate that patients with PH-ILD, BOS and SAPH can safely and effectively use the inhaler to administer LAM-001. If human factors testing reveals usability deficiencies, we may be required to modify the device, develop additional labeling or training tools, or conduct additional studies before the FDA will approve our NDA, any of which could delay our development timeline and increase our costs.

In addition, following any approval of LAM-001, changes to the device, whether initiated by us, the manufacturer or required by a regulatory authority, may require us to make supplemental NDA filings and to conduct additional validation studies before the modified drug-device combination may be used. Any failure to obtain timely regulatory clearance for such changes, or any quality, safety, or performance issue identified with respect to the inhaler following approval, could limit our ability to supply LAM-001 to patients and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have received orphan drug designation in the United States for LAM-001 in BOS, sarcoidosis, pulmonary arterial hypertension and lymphangioleiomyomatosis and in the European Union for LAM-001 in BOS and lymphangioleiomyomatosis, and we may seek orphan drug designation in other indications or for other product candidates in the future. We may be unsuccessful, or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity, for product candidates for which we obtain orphan drug designation.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs or biologics intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, orphan drug designation entitled a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs or biologics for rare diseases, regardless of whether the drugs or biologics are designated for the orphan use. In addition, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the "same drug" and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

In the European Union, a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the European Union when the

application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the European Union, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. We have obtained orphan drug designation in the United States for LAM-001 for the treatment of BOS, sarcoidosis, pulmonary arterial hypertension and lymphangioleiomyomatosis. In addition, we have received orphan drug designation in the European Union for LAM-001 the treatment of BOS and lymphangioleiomyomatosis.

We may seek orphan designation for certain of our other current and future product candidates. However, we may be unsuccessful in obtaining orphan drug designation for these or other product candidates and may be unable to maintain the benefits associated with orphan drug designation. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA or comparable foreign regulatory authorities from approving the same or a different drug in another indication. Even after an orphan drug is granted orphan exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Risks Related to Development and our Dependence on Third Parties

We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.

We currently rely on third-party CROs, academic institutions, study sites, clinical investigators and others to conduct, supervise, and monitor our preclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we currently have or plan to enter into agreements governing the activities of these third parties, we have limited influence over their

actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to develop LAM-001 and other current and future product candidates, or we may not obtain marketing approval for, or commercialize, LAM-001 or our other current and future product candidates in a timely manner or at all.

Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities could be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to the development of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by a pandemic limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for current and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize current and future product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for current and future product candidates may be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may enter into collaborations for our current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development. Our

collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, many of which may be beyond our control.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we plan to conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of current and future product candidates, which could result in additional losses and deprive us of potential product revenue.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We currently rely on CMOs for the production of LAM-001, including for the supply of rapamycin, and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

Because LAM-001 is an inhaled dry powder formulation of rapamycin, any disruption to the supply of rapamycin could halt our entire development program. The need to maintain a supply chain for rapamycin increases our operational complexity and our vulnerability to supply disruptions. We may not be able to secure a backup supplier on commercially reasonable terms. Any significant delay in the supply of rapamycin could considerably delay our clinical development, increase our costs, and have a material adverse effect on our business.

We currently have no plans to build our own clinical or commercial-scale manufacturing capabilities for our product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations, or CMOs, as part of our development of our product candidates. These CMOs will provide drug substance intermediate, device, and drug product that will be subsequently, tested, released, labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our product candidates or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce product candidates in the quantities needed for our clinical trials or, if any current or future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of any current or future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

The facilities used by third-party manufacturers to manufacture current or future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need

to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of any of our product candidates. Additionally, any changes implemented by a new CMO would require substantial investment to qualify and validate the vendor as a suitable third party manufacturer of our development or marketed products. Furthermore, we may be required to conduct comparability assessments, which may include additional human clinical studies, in conjunction with validating the new CMO(s).

If any CMO with whom we contract fails to perform its obligations, it could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current and future product candidates and jeopardize our ability to commence product sales and generate revenue.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates or products. In addition, in the case of CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

As part of their manufacture of our product candidates, our CMO and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If our CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which could significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of any current or future product candidates for use in clinical trials or for commercial supply;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or second sources of supply with alternative suppliers or CMOs to supplement or supply the raw materials, drug substances, intermediates, and drug product necessary for the manufacture of our product candidates, including LAM-001. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

We rely on a single supplier for the dry powder inhaler, and a limited number of suppliers for the raw materials used in our product candidates, and accordingly, any delay, shortage or interruption in the supply of the inhaler or such raw materials, or any contamination in our manufacturing process, could lead to delays in the manufacture and supply of our product candidates.

LAM-001 is administered using a dry powder inhaler. We have entered into a supply agreement with Plastiape S.p.A. that provides us with exclusive rights with respect to the device and rapamycin for LAM-001. We currently rely on Plastiape as our sole supplier for the inhaler. If Plastiape were unable or unwilling to supply the inhaler in accordance with our supply agreement, we would need to identify and qualify an alternative device, which would require significant time, expense and regulatory effort, including potential modifications to our NDA submission and additional validation studies. Any failure by Plastiape to perform its obligations under the supply agreement, or any termination or non-renewal of such agreement, could adversely impact our ability to manufacture and supply LAM-001 for our clinical trials or, if approved, for commercial use, and could have a material adverse effect on our business, financial condition, results of operations and prospects. We do not manufacture or control the inhaler, and any disruption to Plastiape's ability to manufacture or support the device could temporarily affect our ability to supply LAM-001 for our clinical trials or, if approved, for commercial use.

We further rely on third-parties to supply certain raw materials necessary to produce our product candidates for preclinical studies and clinical trials. For example, we rely on third-parties to supply certain reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources. There are a small number of suppliers for certain raw materials that we use to manufacture our product candidates. Certain of our suppliers or their sub-suppliers are international, which exposes us to additional risks including trade restrictions, tariffs, export controls, geopolitical tensions, and potential disruptions to the supply chain that are beyond our control. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our product candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our product candidates, the commercial launch of our product candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our product candidates could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. 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. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize or will be delayed in commercializing our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates, including LAM-001 for the treatment of PH-ILD, BOS and SAPH, from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our clinical trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more additional controlled clinical trials to obtain approval. Additionally, even if the FDA does grant approval for one or more of our product candidates, it may be for a narrower indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical 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 information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our preclinical studies or clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may submit marketing applications in countries other than the United States. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of 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 our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates 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 of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the 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 short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims, including the federal FCA, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act, or ACA, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by HITECH and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 our business activities, including compensation of physicians with stock or equity awards, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing 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 U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services, or HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, 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. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada. 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.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. 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/or impose price controls may adversely affect:

- the demand for our current or 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.

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.

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Compliance with Trade Control laws may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, Trade Control laws prohibit the provision of certain products and services to countries, governments and persons targeted by sanctions.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally intend to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. 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.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We have never commercialized a product. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. We currently plan to work to build our commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Additionally, our beliefs that our products will be commercially viable have not been tested.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, including LAM-001, effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of serious pulmonary disorders, including PH-ILD. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

Tyvaso, sold by United Therapeutics, Inc., and Yutrepia, sold by Liquidia Corporation, are approved drugs for the treatment of PH-ILD. We believe that LAM-001 for the treatment of PH-ILD has the potential to be used in combination with approved therapies and

product candidates in development. We are aware of several product candidates in clinical development for the treatment of PH-ILD, including product candidates in development by AllRock Bio, Apollo Therapeutics, Foresee Pharmaceuticals, Gossamer Bio, Halo Biosciences, Insmed Incorporated, Liquidia Corporation, Pharmosa Biopharm, Pulmovant, Tectonic Therapeutic, and United Therapeutics Corporation. We also anticipate that we would compete with product candidates in development for BOS by Renovion, Sanofi, and Zambon. Several of these product candidates are in Phase 3 registrational trials with potential approval timelines that are ahead of our development timeline for LAM-001, including Insmed's TPIP in a Phase 3 clinical trial for PH-ILD and Liquidia and Pharmosa's L606 in a Phase 3 clinical trial for PH-ILD. In SAPH, we are aware of products marketed for the treatment of PAH which are frequently used off-label in SAPH patients, including drugs manufactured by Bayer, Eli Lilly, Gilead, Johnson & Johnson, Liquidia, Pfizer, and United Therapeutics. We believe that LAM-001 for the treatment of SAPH has the potential to be used in combination with these therapies.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

The companies against which we may compete may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ourselves, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Because of our primary focus on serious pulmonary disorders, if our product candidates achieve marketing approval, we expect to seek premium pricing.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either their product or a specific indication before we are able to enter the market.

Even if any of our product candidates receives marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance could harm our business and could require us to seek additional financing.

Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will

be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years and biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Moreover, our positioning of LAM-001 as an additional therapy may limit our pricing power and reimbursement potential, as third-party payors may view LAM-001 as an incremental addition to existing regimens and may impose step therapy, prior authorization or other access restrictions. Physicians may also be reluctant to add a new agent to complex treatment regimens in seriously ill patient populations where polypharmacy risks are heightened.

Our business, operational and financial goals may not be attainable if the market opportunities for our products are smaller than we expect. Our internal research and third-party estimates may not accurately reflect the market opportunities for LAM-001 or our other product candidates today or in the future.

The total market opportunities that we believe exist are based on a variety of assumptions, calculations and estimates, including the size of the addressable patient population in applicable jurisdictions, the penetration of other drugs in these markets, the number of patients we will test in clinical trials, the price we will be able to charge for our products and the total annual number of patients with PH-ILD, BOS or SAPH. In addition, we have relied on third-party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of respiratory disease patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the number of deaths caused by PH-ILD, BOS or SAPH, and the expected growth in related drug therapy and diagnostic markets. Our internal research and estimates on market opportunities include the use of independent sources, but any or all of our assumptions and/or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our products or such patients becoming difficult to identify and access, limited reimbursement for our products, pricing pressure due to availability of alternative drugs or an inability to obtain the necessary regulatory

approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we may not attain our business, operational and financial goals.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and 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 the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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 business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection, trademarks, and confidentiality agreements to protect the intellectual property related to our product candidates and development programs. Our success depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our present and future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future

product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. 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 position of biopharmaceutical companies is generally uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application.

Moreover, we may in the future be subject to a third-party pre-issuance submission of prior art to the USPTO. We may also become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before

or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidate(s) for an indication that is outside of the methods of use claimed in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their products for indications that are covered by our patents, clinicians may prescribe these competitor products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

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

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

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

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

The United States has enacted and implemented wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to

obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out of our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such

patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms.

Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidate(s), or the use of our product candidate(s). As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidate(s) or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidate(s).

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

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Furthermore, as the patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. 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. In that event, we may face commercial competition, which could harm our business. We cannot provide any assurances that third-party patents do not exist which might be enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to

commercialize our product candidates. In each of these cases, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

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 our 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. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may develop or license intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to future licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies may provide funding, facilities, personnel, or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may retain rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products. For example, research resulting in future in licensed patent rights and technology that was funded in part by the U.S. government could result in the government having certain rights, or march in rights, to such patent rights and technology which may permit the government to disclose our confidential information to third parties and to exercise march in rights to use or allow third parties to use our licensed technology, potentially on unfavorable terms or without adequate compensation.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. 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 and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There

is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

Similarly, 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

We employ individuals and retain independent contractors and consultants, or in the future, may employ individuals and retain independent contractors and consultants, who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, independent contractors, consultants, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such persons' former companies or other third parties. We may also be subject to claims that such persons or other third parties have an ownership interest in our intellectual property. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while we require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights with respect to certain clinical programs.

We are party to certain license agreements with respect to certain of our product candidates outside of our LAM-001 clinical program pursuant to which we were granted rights to intellectual property in connection with the development, manufacture and commercialization of such product candidates. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, and in the event of termination we may not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the priority of invention of patented technology.

If disputes over intellectual property and other rights 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 product candidates and that could harm our business.

In addition, our license agreements do, and we expect that future license agreements will impose various diligence, milestone payment, royalty, insurance and/or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology, and could compromise our development and commercialization efforts for our product candidates.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. 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 harm 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.

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

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidates or any other 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our 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.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. 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, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we require all of our employees and consultants 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. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, defending and enforcing patents and trademarks on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent or trademark applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign 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 patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, 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. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. In addition, many countries limit the enforceability of patents against government agencies or government contractors. 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.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidate(s). While we will endeavor to try to protect our technologies and product candidate(s) with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and unpredictable.

In addition, geopolitical actions in the United States and in other countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents or those of any future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. We rely on our outside counsel or third-party vendors to pay these fees. The USPTO, CIPO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within

prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our present and future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to our Business Operations

We will be required to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need and to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if our product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial and human resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, as the competition for individuals in serious pulmonary disorder product development is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and the expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. Our senior management may terminate their employment with us at any time, and we do not maintain “key person” insurance for any of our employees.

The Acquisition resulted in a combined management team that is small relative to our development ambitions. We are heavily dependent on a limited number of individuals with specialized expertise in serious pulmonary disorders. The loss of one or more of these individuals, particularly during the critical post-Acquisition integration period, could significantly delay our clinical development programs. Competition for individuals with this specialized expertise is intense, and we may not be able to recruit suitable replacements on acceptable terms or in a timely manner.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management 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 our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate 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 and biotechnology companies for similar personnel. 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 research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Following the Acquisition, certain of our employees who previously worked at a private company are now subject to public company compliance obligations, and any failure to comply with these obligations could expose us to regulatory risk and reputational harm.

As a result of the Acquisition, a number of individuals who previously operated in a private company environment are now employees or officers of a publicly traded company and are subject to public company compliance obligations, including compliance with our insider trading policy, Section 16 reporting requirements under the Securities Exchange Act of 1934, Regulation FD restrictions on selective disclosure of material nonpublic information, and quiet period restrictions around SEC filings. These individuals may not have prior experience with public company compliance requirements.

We have implemented onboarding and training programs to educate former Orphai employees regarding these obligations. However, there can be no assurance that all individuals will fully understand or consistently comply with these requirements, particularly during the initial post-Acquisition integration period. Any inadvertent violation of insider trading laws, Section 16 reporting obligations, or Regulation FD could result in SEC enforcement action, personal liability for the individuals involved, and reputational harm to the company. Such violations could also undermine investor confidence in our corporate governance practices and adversely affect the trading price of our common stock.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently maintain product liability insurance with coverage in the aggregate and a per incident limit at an amount that we believe is adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we re-initiate our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to our Securities and our Status as a Public Company

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates ;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;

- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common stock or other securities or other reasons may in the future cause us to become the target of securities litigation or stockholder activism.

Securities litigation and stockholder activism, including proxy contests, could result in substantial costs and divert management's and the Board's attention and resources from our business. The potential of a proxy contest or other stockholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements registering the issuance of all shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market following vesting, exercise and/or settlement (as applicable) of the equity awards and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Furthermore, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Finally, in connection with the execution of the Agreement and Plan of Merger, or the Merger Agreement, dated as of May 17, 2026, by and among the Company, Orphai Therapeutics, LLC, a Delaware limited liability company and wholly owned subsidiary of Orphai Holdings Therapeutics, Inc., a Delaware corporation, Phoenix Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Phoenix Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, certain of our directors and officers, as well as certain of the directors, officers and stockholders of Orphai, each as of immediately prior to the Acquisition, entered into lock-up agreements for a period ending on the earlier of (i) 12 months after the closing of the Acquisition and (ii) the issuance by us of a press release announcing (a) top line data from the ongoing LAM-001 Phase 2 trial in BOS or (b) the termination or suspension of such trial, whichever occurs first, pursuant to which each such stockholder will be subject to restrictions on the sale or transfer of shares of our common stock and Series C Preferred Stock held by each such stockholder, including those shares received by directors and officers in the Acquisition, subject to certain limited exceptions as set forth in such lock-up agreements, and provided that such restrictions will be terminated upon the termination of such party's employment or service as a member of our board of directors. In addition, following the date that is 180 days after the closing of the Acquisition, 5% of the aggregate number of shares of common stock owned by such party at such time, and on a monthly basis thereafter, will be released from the lockup restrictions. Upon expiration of this lockup period, these shares will become eligible for sale in the public market. Pursuant to the Merger Agreement and the registration rights agreement that we entered into pursuant to the 2026 Private Placement, we are obligated to prepare and file a resale registration statement with the SEC to register the resale of shares of our common stock underlying the Series C Preferred Stock and warrant to purchase shares of Series C Preferred Stock. We will use reasonable best efforts to cause this registration statement to be declared effective by the SEC. Once the registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to (i) the approval of the Company Stockholder Matters (as defined below), (ii) the approval of the Nasdaq Listing Application (as defined below) and (iii) any beneficial ownership limitations set by the holder of Series C Preferred Stock. Certain additional holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline.

In addition, we have filed a shelf registration statement on Form S-3, or the Shelf Registration Statement, which permits us to sell from time to time up to $200.0 million of additional shares of our common stock or other securities in one or more offerings. In particular, we may offer and sell up to $75.0 million of shares of our common stock from time to time pursuant to the Controlled Equity Offering^{SM} Sales Agreement dated December 18, 2024, or the Sales Agreement, that we have entered into with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC. During the six months ended June 30, 2026, we utilized our ATM program to raise net proceeds of approximately $20.3 million by issuing 526,435 shares of common stock. Depending on market liquidity at the time, sales of our common stock pursuant to the Sales Agreement, or other sales of our common stock or other securities under the Shelf Registration Statement, may cause the trading price of our common stock to decline.

Furthermore, we have warrants currently outstanding that will be exercisable beginning on the trading day following the earlier of our public announcement of (a) top line data from the ongoing LAM-001 trial in BOS and (b) the termination or suspension of such LAM-001 trial in BOS and through the 30th day following such public announcement to purchase shares of common stock. To the extent that these warrants are exercised, or to the extent we issue additional shares of common stock in the future, as the case may be, there will be further dilution to holders of shares of the common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our stockholders may realize little or no value from the divestiture of our legacy assets, and as a result our stock price may decline, we could be subject to litigation, and our business may be adversely affected.

We sold our legacy small molecule protease inhibitor portfolio to Lighthouse, which is a newly organized, private development stage company in the start-up phase, and has only recently commenced its operations. There is currently no existing public market for the shares of Lighthouse's common stock, and there can be no assurance that an active public market will ever develop. The absence of an active public market for these securities would make it difficult for us to sell the shares of Lighthouse's common stock and realize any value from them. To date, Lighthouse's operations have been primarily limited to organizing and staffing its company and completing the acquisition of our legacy assets. Accordingly, it is difficult if not impossible to predict Lighthouse's future performance or to evaluate its business and prospects, or ability to develop our legacy assets. For these and other reasons, our stockholders may realize little or no value from the divestiture of our legacy assets.

The divestiture of our legacy assets could result in litigation against us, including litigation arising from or related to the value, received in the sale of our legacy assets to Lighthouse. For example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our small molecule protease inhibitor portfolio, others because they were interested in our bone-targeting drug platform. Thus, certain stockholders may have attributed substantial financial value to our legacy assets or NOV004. If our stockholders believe that the financial value which is or may be received by us or them from the divestiture of our assets is inadequate, our stock price may decline and litigation may occur. As a result of these and other factors, we may be exposed to a number of risks, including declines or fluctuations in our stock price, additional legal fees, and distractions to our management caused by activities undertaken in connection with resolving any disputes related to these transactions. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Changes in tax law could adversely affect our business and financial condition.

We are subject to federal, state and local income and other taxes in the United States and in foreign jurisdictions because of the scope of our operations. New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the U.S.

government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act that (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other taxing authorities with respect to this and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business. To the extent that any such changes in tax laws and regulations have a negative impact on us, including as a result of related uncertainty, our business, financial condition, results of operations and cash flows may be materially and adversely impacted and we may be required to implement changes to minimize increases in our tax liability.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. NOLs generated in Italy are subject to Italian tax laws and deductibility of such Italian NOLs are limited to 80% of taxable income. As of December 31, 2025, we had federal net operating loss carryforwards of approximately $253.3 million, of which $237.5 million will not expire and $15.8 million begin expiring in 2034. As of December 31, 2025, we also had state net operating loss carryforwards of approximately $34.8 million which begin to expire in 2034. Additionally, we have federal tax credits of approximately $10.4 million which begin to expire in 2036 and state tax credits of approximately $3.0 million which do not expire.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Following the approval of the Company Stockholder Matters, the Acquisition will result in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after approval of the Company Stockholder Matters. Orphai's NOL carryforwards may also be subject to limitations as a result of prior shifts in equity ownership and/or the Acquisition. We may also have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of Orphai we have acquired as a result of the Acquisition may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have incurred and expect to continue incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, as a private company. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance,

which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often 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.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. Depending upon our filer status, we could also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as required by Section 404(b). To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

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

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

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

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

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions.

Risks Related to the Acquisition

Pursuant to the terms of the Acquisition, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series C preferred stock into shares of our common stock. We must also obtain stockholder approval of an amendment to our certificate of incorporation to increase the number of shares we are authorized to issue. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Merger Agreement and the 2026 Private Placement purchase agreement, as promptly as practicable following the date of the Merger Agreement and pursuant to the Nasdaq Stock Market Rules, we will call and hold a meeting of our stockholders to obtain the requisite approval from our legacy stockholders for, among other things, (i) the approval, in accordance with certain of the rules of Nasdaq of the conversion of the Series C Preferred Stock into shares of our common stock, or the Conversion Proposal, (ii) the approval of the transactions contemplated by the Merger Agreement and the 2026 Private Placement in accordance with applicable Nasdaq listing rules, or the Nasdaq Proposals, (iii) the amendment of our certificate of incorporation to authorize an increase to the number of authorized shares of our common stock from 250,000,000 to up to 800,000,000 shares of common stock (in July 2026, the Board determined to recommend that the stockholders approve an increase in the number of authorized shares of our common stock to 275,000,000 shares), or the Charter Amendment Proposal and, together with the Conversion Proposal and the Nasdaq Proposals, the Company Stockholder Matters, (iv) the approval of (A) the 2026 Equity Incentive Plan, which will provide for new awards for a number

of shares of our common stock not exceeding the total of (x) 15% of our fully diluted shares of capital stock outstanding immediately after the 2026 Private Placement, plus (y) any shares covered by our outstanding awards granted under a prior equity incentive plan that, after the date the 2026 Equity Incentive Plan becomes effective, are not issued because the award expires or otherwise terminates without all of the shares covered by the award having been issued, are not issued because the award is settled in cash, are forfeited or repurchased because of the failure to vest, or are reacquired or withheld to satisfy a tax withholding obligation or the purchase or exercise price, and which will include an annual increase pursuant to an "evergreen" provision providing for an annual increase of up to 5% of the total number of our fully diluted shares of capital stock outstanding as of the day prior to such increase and (B) the 2026 Employee Stock Purchase Plan, with a total pool of shares of our common stock not exceeding 1% of our fully diluted shares of capital stock outstanding immediately after the 2026 Private Placement, and which shall include an annual increase pursuant to an "evergreen" provision providing for an annual increase of up to 1% of the total number of our fully diluted shares of capital stock outstanding as of the day prior to such increase and (v) such other changes or approvals as may be mutually agreed by us and Orphai. If we fail to receive sufficient proxies to constitute a quorum or to obtain the required vote on the Company Stockholder Matters and/or our Nasdaq Listing Application is not approved, we would be required to adjourn the meeting one or more times for up to 30 days per adjournment. If stockholder approval of the Company Stockholder Matters or approval of the Nasdaq Listing Application are still not obtained following such adjournment(s), we will be obligated to continue soliciting stockholder approval at subsequent annual or special meetings of our stockholders, held at intervals of no more than six months, until such approvals are obtained, which would be time consuming and costly.

There can be no assurance that our legacy stockholders will approve the Company Stockholder Matters. If our legacy stockholders do not approve the Charter Amendment Proposal, we would be unable to issue the additional shares of our common stock necessary to complete the conversion of Series C Preferred Stock into our common stock, and may be unable to satisfy our other capital needs, which could have a material adverse effect on our business, financial condition, and prospects.

Additionally, if at any time after the earlier of (i) the approval of the Company Stockholder Matters or (ii) the date that is six months following the initial issuance date of the Series C Preferred Stock, we fail to deliver to the holders of the Series C Preferred Stock shares of common stock underlying such shares of Series C Preferred Stock, (other than in certain circumstances set forth in the Certificate of Designation, as defined below) the holders of the Series C Preferred Stock would be entitled to require us to settle such undelivered shares for cash in an amount equal to the fair value of such undelivered shares of Common Stock at such time, as described in the Certificate of Designation of Preferences, Rights and Limitations of the Series C Preferred Stock, or the Certificate of Designation. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series C Preferred Stock, it could materially affect our results of operations, business and financial condition.

Failure to obtain approval of the Nasdaq Listing Application could materially affect our results of operations, business and financial condition.

Pursuant to the Merger Agreement, in order to permit the waiver of the beneficial ownership limitations applicable to the Series C Preferred Stock and take other actions following the consummation of the Acquisition, which would constitute a "change of control" under Nasdaq Listing Rule 5110(a), we are required to use our reasonable best efforts to file an initial listing application for our common stock on Nasdaq, or the Nasdaq Listing Application. The Nasdaq Listing Application must be conditionally approved prior to the date of our stockholder meeting to approve the Company Stockholder Matters. If we fail to meet the Nasdaq listing requirements and Nasdaq does not approve the Nasdaq Listing Application, we will be required to adjourn our stockholder meeting to approve the Company Stockholder Matters one or more times for up to 30 days per adjournment, continue to use our reasonable best efforts to obtain approval of the Nasdaq Listing Application and to continue soliciting stockholder approval of the Company Stockholder Matters at subsequent annual or special meetings of our stockholders, held at intervals of no more than six months, until such approval and the approval of the Company Stockholder Matters are obtained, which would be time consuming and costly. Additionally, if at any time after the earlier of (i) the approval of the Company Stockholder Matters or (ii) the date that is six months following the initial issuance date of the Series C Preferred Stock, we fail to deliver to the holders of the Series C Preferred Stock shares of common stock underlying such shares of Series C Preferred Stock, (other than in certain circumstances set forth in the Certificate of Designation) the holders of the Series C Preferred Stock would be entitled to require us to settle such undelivered shares for cash in an amount equal to the fair value of such undelivered shares of Common Stock at such time, as described in the Certificate of Designation. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series C Preferred Stock, it could materially affect our results of

operations, business and financial condition. We cannot assure you that we will be able to meet Nasdaq's initial listing standards. Furthermore, if we fail to obtain approval of the Nasdaq Listing Application, we may be unable to execute on our plans for the Company following the Acquisition, which could materially affect our results of operations, business and financial condition.

There is no guarantee that the Acquisition will increase stockholder value.

In May 2026, we consummated the Acquisition, pursuant to which we acquired Orphai, and we closed the 2026 Private Placement. We cannot guarantee that implementing the Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Acquisition poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Acquisition to our stockholders.

The failure to successfully integrate the businesses of the Company and Orphai in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Our ability to successfully integrate the operations of the Company and Orphai will depend, in part, on our ability to realize the anticipated benefits from the Acquisition. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Acquisition may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the integration of the Company's and Orphai's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. There can be no assurance that we will effectively manage the increased complexity of our business without experiencing operating inefficiencies or control deficiencies. Delays encountered in the integration process could have a material adverse effect on our expenses, operating results and financial condition, including the value of shares of our common stock.

We expect to incur substantial expenses related to the integration of Orphai.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Acquisition and the integration of Orphai. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including accounting and finance, billing, payroll, and benefits. Both the Company and Orphai have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement, and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Acquisition, and the amount and timing of such charges are uncertain at present.

General Risk Factors

Our business, operations and clinical development plans and timelines, as well as the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers, equipment suppliers and others, could be adversely affected by the effects of health epidemics.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. The effects of government orders may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there

is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

If our information systems or data, or those of our collaborators, contractors, consultants or other third parties with whom we work, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or, collectively, process, proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets and clinical trial data, or, collectively, sensitive information.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, attacks enhanced or facilitated by artificial intelligence, or AI, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Future or past business transactions (such as acquisitions or mergers) expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also 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.

Remote work has increased risks to our information systems and data, as personnel utilize network connections, computers and devices outside of our premises or network.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, this could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such an actual or perceived security incident could also cause us to experience other adverse consequences, such as: loss of, or damage to, our data or applications, inappropriate disclosure of confidential or proprietary information, legal liability, exposure to litigation (including class claims) and regulatory enforcement action (for example, investigations, fines,

penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, harm to our competitive position, reputational damage, and delay in the further development and commercialization of our product candidates.

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 sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

In addition to experiencing a security 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 the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous privacy and data security laws, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, many states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services if we become subject to these laws. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act ("CCPA") applies to personal data of consumers, business representatives, and employees who are California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other U.S. state comprehensive consumer privacy laws exempt certain personal data processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work should we become subject to these laws. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels, and we expect more governments to pass similar laws in the future. The evolving patchwork of local, state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") the United Kingdom's General Data Protection Regulation ("UK GDPR") (collectively, "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and India's Information Technology Act and supplementary rules, impose strict requirements for

processing personal data. The EU GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European Economic Area ("EEA") residents. Among other things, the EU GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data over prior EU law and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The EU GDPR also provides for substantial fines for breaches and violations (up to the greater of €20 million or 4% of annual global revenue). The EU 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 EU GDPR.

We increasingly use artificial intelligence and machine learning tools across our operations and business functions, and we expect our use of such tools to expand over time. While we believe that the responsible use of AI tools can enhance our operational efficiency, these tools present risks that could adversely affect our business. AI-generated outputs may be inaccurate, incomplete, or misleading, and reliance on such outputs without adequate human oversight could result in errors in regulatory submissions, clinical or scientific analyses, contractual provisions, or public disclosures. In addition, the input of proprietary, confidential, or sensitive information into third-party AI platforms could result in the inadvertent disclosure of trade secrets, attorney-client privileged materials, or material nonpublic information. The regulatory landscape governing the use of AI in the life sciences and pharmaceutical industries is rapidly evolving, and new laws, regulations, or guidance — including those arising from the current administration's policy initiatives — could impose additional compliance obligations, restrict certain uses of AI tools, or increase our exposure to regulatory enforcement actions or litigation. Any failure to adequately govern our use of AI tools could result in reputational harm, regulatory scrutiny, or legal liability. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries as part of ordinary course clinical trials. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are considered "foreign persons" and majority owned by, organized under the laws of, primarily resident in, or a contractor of a covered person or country of concern, as applicable) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In addition to data privacy and security laws, we are and may in the future become bound by contractual obligations and industry standards 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. Regulators are increasingly scrutinizing these statements, and if these statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy obligations) are quickly changing, becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change aspects of our business model or our clinical trials.

Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to power shortages, telecommunications failures, water shortages, civil unrest, labor disputes, violence, earthquakes, floods, hurricanes, typhoons, fires, extreme weather conditions, infectious disease, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates . Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our common stock could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

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

None.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information

None.

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 and such Exhibit Index is incorporated herein by reference.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Filing Date	Number	
2.1*	Agreement and Plan of Merger, dated May 17, 2026, by and among Quince Therapeutics, Inc., Phoenix Merger Sub I, Inc., Phoenix Merger Sub II, LLC, Orphai Therapeutics, LLC, and Orphai Holdings Therapeutics, Inc.	8-K	5/18/2026	001-38890	
3.1	Amended and Restated Certificate of Incorporation	8-K	5/13/2019	001-38890	
3.2	Certificate of Amendment to the registrant's Certificate of Incorporation, effective August 1, 2022	8-K	8/1/2022	001-38890	
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	4/9/2026	001-38890	
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	6/26/2026	001-38890	
3.5	Amended and Restated Bylaws	8-K	8/1/2022	001-38890	
3.6	Amendment to Amended and Restated Bylaws	10-K	4/10/2026	001-38890	
3.7	Certificate of Designation of Series C Non-Voting Convertible Preferred Stock	8-K	5/18/2026	001-38890	
4.1	Form of Warrant to Purchase Series C Non-Voting Convertible Preferred Stock or Common Stock	8-K	5/18/2026	001-38890	
10.1*	Form of Securities Purchase Agreement, dated as of May 18, 2026, by and among Quince Therapeutics, Inc. and each investor listed on Exhibit A thereto	8-K	5/18/2026	001-38890	

10.2*	Form of Registration Rights Agreement, by and among Quince Therapeutics, Inc. and certain investors signatory thereto	8-K	5/18/2026	001-38890	
10.3+	Employment Letter between the Company and Brigette Roberts, effective May 18, 2026	8-K	5/18/2026	001-38890	
10.4+	Employment Letter between Orphai Therapeutics Inc. and Brigette Roberts, effective May 12, 2026.	8-K	5/18/2026	001-38890	
10.5+	Retention Bonus Agreement dated May 17, 2026 between the Company and Dirk Thye	8-K	5/18/2026	001-38890	
10.6+	Retention Bonus Agreement dated May 17, 2026 between the Company and Brendan Hannah	8-K	5/18/2026	001-38890	
10.7†	License and Supply Agreement, dated May 14, 2026, by and between Plastiape S.p.A. and Orphai Therapeutics, Inc.				X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
32.1#	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2#	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data file as its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101				

+ Management contract or compensatory plan or arrangement.
† Portions of this agreement (indicated by asterisks) have been omitted because the registrant has determined they are not material and would likely cause competitive harm to the registrant if publicly disclosed.
* Certain schedules, annexes, and attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to provide, on a supplemental basis, a copy of any omitted schedules and attachments to the Securities and Exchange Commission or its staff upon request.
# In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference

into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

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.

Quince Therapeutics, Inc.

Date: August 14, 2026

By: /s/ Dirk Thye
Dirk Thye
Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

Date: August 14, 2026

By: /s/ Brendan Hannah
Brendan Hannah
Chief Business Officer, Chief Operating Officer, and Chief Compliance Officer
(Principal Financial Officer)

Exhibit 10.7

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

LICENSE AND SUPPLY AGREEMENT

This License and Supply Agreement (the "**Agreement**"), dated as of May 14th, 2026 ("**Effective Date**"), is by and between:

PLASTIAPE S.p.A., organized and existing under the laws of Italy, registered with the Trade Register of Lecco under number 00231050139 with offices at via 1° Maggio, 8, I-23875 Osnago, Italy, duly represented by its Managing Director, Mr. Alfredo Masuello (the "**Supplier**"); and

ORPHAI THERAPEUTICS, Inc, organized and existing under the laws of Delaware, having a principal place of business at 530 Old Whitfield Street, Guilford, Connecticut 06437, duly represented by its Chief Financial Officer, Mr. Paul Boni (the "**Customer**").

Supplier and Customer may be referred to individually as "**Party**" and collectively as "**Parties**".

PREAMBLE

Supplier is engaged in the design, manufacture and supply of inhalation devices.

Customer is a biotechnology company that develops pharmaceutical products.

Customer wishes to purchase the device(s) manufactured by Supplier and Supplier is willing to sell such Products to Customer, on the terms and conditions set out in this Agreement.

THEREFORE,

1. DEFINITIONS

"**Affiliate(s)**" means, with respect to a Party, any legal entity that directly or indirectly Controls, is Controlled by, or is under common Control with that Party, now or in the future. For purposes of this definition only, "**Control**" means, with respect to an Affiliate, directly or indirectly, (a) ownership of more than fifty percent (50%) of the voting securities or other voting interests of an entity; or (b) the right to appoint or remove a majority of the members of its board of directors (or equivalent governing body); or (c) the power to direct the management or policies of such entity, whether through ownership, by contract or otherwise. For clarity, ordinary minority-investor protective veto rights alone do not constitute Control.

"**Contract Year**" shall mean the twelve (12) month period during the Term commencing on January 1 and ending on December 31 of each calendar year; provided, however that the first Contract Year shall be the period beginning on the Effective Date and ending on December 31st in the calendar year in which the Effective Date occurs and the last Contract Year shall be the period beginning on January 1 and ending on the effective date of expiration or termination of this Agreement.

"**Control**" shall mean, with respect to Intellectual Property Rights and regulatory documentation (including Registrations), that a Party or one of its Affiliates owns or has a license or sublicense to such Intellectual Property Rights or regulatory documentation and has the ability to provide to, grant a license or sublicense to, or assign its right, title and interest in and to, such Intellectual Property Rights or documentation as provided for in this Agreement without violating the terms of any other agreement or other arrangement with any third party.

"**Customer's Finished Product**" means any medicinal product, medical device, or drug–device combination product developed, assembled, filled, packaged, labelled, tested, released, marketed, or otherwise supplied by Customer, into which the Product is incorporated or with which the Product is intended to be used. Customer's Finished Product includes all drug substances, excipients, formulations, components, packaging labelling, stability data, clinical performance, regulatory submissions, and post-market obligations relating to such product, all of which remain under Customer's sole responsibility.

"**Exclusivity Fee**" means [*].

"**Exclusivity Minimum Retention Quantities**" means, with respect to each Post-Launch Exclusivity Year, for each Molecule/API in Schedule 2, the minimum quantity of the Product that Customer must order under P.O.s in such Post-Launch Exclusivity Year (or as may be agreed between the Parties) to retain exclusivity, measured in the units specified for each Molecule/API in Schedule 2.

"**Exclusivity Term**" means, for each Molecule/API granted exclusivity, the period commencing on the Effective Date and continuing for the duration specified in Schedule 2, unless earlier terminated or lapses in accordance with Section 3.3.4.; provided that any Exclusivity Minimum Retention Quantities apply only after Launch.

"**Indication/Field**" means, if specified in Schedule 2, the disease area, condition, or labelled use that narrows the scope of a Molecule/API exclusivity.

"**Launch**" shall mean, with respect to the Product, the date on which Customer's Finished Product is first shipped for commercial sale by Customer to a third party in the Territory.

"**Measurement Period**" means each Post-Launch Exclusivity Year, unless otherwise stated for a Molecule/API in Schedule 2.

"**Notified Body**" means a conformity assessment body designated by an EU Member State and notified to the European Commission under Regulation (EU) 2017/745 (MDR) to perform conformity assessments, technical documentation reviews, surveillance activities and unannounced audits for medical devices.

"**Post-Launch Exclusivity Year**" means each successive twelve (12) -month period commencing on the first anniversary of Launch and each anniversary thereof.

"**Product**" means Supplier's [*] inhalation devices as further described in Schedule 1.

"**Registration**" means any marketing authorization, listing, import license, filing, notification, or similar approval required to place the Product on the market in a jurisdiction.

"**Registration Cost Sharing Addendum**" means a short addendum or purchase order that specifies the country(ies), activities, timelines, and Customer's participation in relevant costs for Registration outside the Territory of Registration.

"**Reserved Molecules**" means the molecules/active pharmaceutical ingredients ("**APIs**") listed in Schedule 2 for which Supplier has pre-existing exclusivity commitments to third parties, or which Supplier otherwise restricts from use with the Product by this Customer, for the period stated.

"**Regulatory Authority**" means any governmental authority responsible for regulating medical devices, medicinal products, drug–device combination products, or related manufacturing activities in a given jurisdiction, including without limitation the FDA (USA), MHRA (UK), CDSCO (India), EMA (EU), and any EU Competent Authority.

"**Specifications**" means the technical specifications applicable to the Products as set forth in Schedule 1.

"**Territory**" means worldwide.

"**Territory of Registration**" means the jurisdictions in which the Product is registered or otherwise lawfully placed on the market by Supplier as legal manufacturer, currently consisting of [*]. At Customer's written request, Supplier may support the registration or placing on the market of the Product in additional jurisdictions, subject to Supplier's prior written acceptance and the Parties' good-faith agreement on all applicable regulatory, technical and cost responsibilities, including any regulatory agent fees, governmental fees, testing, samples, translations and Supplier's service fees. Supplier shall have no obligation to obtain, maintain or renew registrations outside the Territory of Registration unless expressly agreed in writing.

2. **SUPPLY OF PRODUCT – SUBCONTRACTING - PURCHASE ORDERS - PURCHASE ORDER'S WITHDRAWAL OR CANCELLATION**

2.1 Capacity-based Supply Commitment - Subcontracting

2.1.1 Capacity-based Supply Commitment. Supplier shall manufacture and supply to Customer (and/or its Affiliates and other designees, as applicable), and Customer (and/or its Affiliates and other designees, as applicable) agrees to purchase from Supplier, Customer's (and/or its Affiliate's and/or other designee's, as applicable) orders for Product during the Term as set forth in a P.O. (defined below) hereunder, in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing but subject to Supplier's obligations of exclusivity and to supply each accepted P.O., Supplier's obligation to supply Products is subject at all times to Supplier's designed manufacturing capacity. Supplier shall not be required to (i) expand or modify its manufacturing facilities, (ii) operate beyond normal operating conditions, or (iii) prioritize Customer over other customers in order to meet Customer's requirements.

2.1.2 Subcontracting. Supplier shall not subcontract any of its manufacturing obligations hereunder without the prior written consent of Customer, such consent not to be unreasonably withheld, conditioned or delayed. With respect to any manufacturing subcontracting, Supplier shall remain responsible for all obligations hereunder and fully guarantees and warrants the related performance (in accordance with this Agreement) of any responsibilities so subcontracted. Without limiting the foregoing, Supplier shall cause any and all such subcontractors (including any Affiliates or third parties) to comply with the terms and conditions of this Agreement (including with respect to any and all audit and inspection rights of Customer), and such subcontractors shall be so bound in writing.

2.2 Purchase Order Submission and Acceptance Process. Customer may order Products from time to time by submitting written purchase orders (each, a "**P.O**.") specifying the type and quantity of Products being ordered, the desired delivery date, and the delivery location. Each P.O. constitutes an offer by Customer to purchase the Products from Supplier in accordance with and subject to the terms of this Agreement. Within [*] following receipt of a P.O., Supplier shall notify Customer in writing whether such P.O. is accepted in full, accepted in part, or rejected. Supplier shall use reasonable best efforts to accept each P.O. submitted by Customer. If Supplier rejects a P.O., Supplier shall, at the time of such rejection, provide written notice setting forth a reasonable explanation for such rejection. If Supplier fails to provide such written explanation, Supplier shall be obligated to accept such P.O. No P.O. shall be binding upon Supplier unless and until accepted by Supplier in writing. Upon Supplier's acceptance of a P.O., whether in full or in part, Supplier shall manufacture and supply the accepted quantities of Products in accordance with the terms of this Agreement and the applicable P.O. confirmation.

2.3 Priority of Agreement Over P.O. Terms. Customer acknowledges that all standard terms and conditions in P.O.s are superseded by this Agreement, are objected to and shall be of no effect, unless expressly accepted by Supplier in writing.

2.4 Estimated Delivery Date. Upon acceptance of a P.O., Supplier shall as soon as practicable inform Customer of the delivery date of the Products. Supplier shall use its best efforts to deliver the Products on the indicated

delivery date and within the indicative manufacturing lead-time (subject to the terms of Schedule 4). The indicative manufacturing lead-time is set forth in Schedule 4.

2.5 Withdrawal or Cancellation of P.O. Customer may withdraw or cancel a P.O. only before it is accepted in writing by Supplier and provided Supplier has not commenced manufacturing of the Products covered by such P.O. In no event may Customer withdraw or cancel a P.O. after Supplier's acceptance or after manufacturing has commenced. Notwithstanding the foregoing, if Customer cancels or defers a P.O. with less than the aforementioned notice, then Supplier agrees to use commercially reasonable efforts to comply with such unplanned changes (including to use best efforts to minimize any amounts that would otherwise be payable by Customer hereunder).

3. FORECAST – MINIMUM PURCHASE COMMITMENT – EXCLUSIVITY AND INDICATION-SPECIFIC RESTRICTIONS

3.1 Forecast. Commencing [*] prior to anticipated Launch, Customer shall submit to Supplier, on a rolling basis no less frequently than once every [*], a forecast of the estimated volume to be purchased with respect to each Product for the following [*] period (the "**Forecast**"). Customer shall prepare the Forecast in good faith and using reasonable commercial assumptions and shall promptly notify Supplier of any material anticipated deviation. The Forecast shall be non-binding and shall not constitute a commitment to purchase or to manufacture Products. Only P.O.s accepted by Supplier in writing shall be binding. Supplier shall use the Forecast solely for capacity and production planning and shall use commercially reasonable efforts to ensure availability of manufacturing capacity to accept P.O.s submitted in line with the Forecast. P.O.s submitted within [*] of the applicable Forecasted quantities shall be given priority acceptance and shall not be rejected due to capacity constraints. For the avoidance of doubt, batch size, batch documentation, quality and regulatory release activities are determined exclusively based on accepted P.O.s and shall not be initiated on the basis of any Forecast.

3.2 Minimum Purchase Commitment. Supplier and Customer may agree on a minimum quantity of Products to be purchased over a certain period of time (the "**Minimum Purchase Commitment**"), as it may be specified in Schedule 4.

3.3 Exclusivity and indication specific restrictions.

3.3.1 No Implied Exclusivity. Except as expressly stated in this Section 3.3 and Schedule 2 (Exclusivity & Indication Specific Restrictions), nothing in this Agreement shall be construed as granting Customer any exclusivity, field restriction, or supply commitment.

3.3.2 Grant and Scope of Exclusivity. Subject to Sections 3.3.4 and 3.3.5 and Schedule 2, Supplier and its Affiliates hereby grant to Customer an exclusive right, during the Exclusivity Term, to purchase the Product solely for use with the applicable Molecule/API for the applicable Indication/Field in the Territory as further stated in Schedule 2.

3.3.3 Protection of Exclusivity.

3.3.3.1 No Conflicting Rights as of the Effective Date. Supplier and its Affiliates represent and warrant that, as of the Effective Date, neither Supplier nor its Affiliates has granted to any third party any right, license or option under any Intellectual Property Rights Controlled by Supplier or its Affiliates that would enable such third party to make or have made the Product for the Molecule/API in the Territory.

3.3.3.2 Exclusivity Covenant. Supplier and its Affiliates hereby covenant that, during the Exclusivity Term applicable to the applicable Molecule/API, neither Supplier nor its Affiliates shall: (i) supply the Product to any third party for use with such Molecule/API in the Territory, or; (ii) grant to any third party any right, license or option under any

Intellectual Property Rights Controlled by Supplier or its Affiliates that would enable such third party to make or have made the Product for such Molecule/API in the Territory.

3.3.4 Conditions to Exclusivity.

3.3.4.1 Compliance with Exclusivity Minimum Retention Quantities. As a condition to the grant and continued effectiveness of exclusivity under this Agreement after Launch, Customer shall, for each applicable Molecule/API and Measurement Period, comply with the Exclusivity Minimum Retention Quantities set forth in Schedule 2, subject to the cure rights and exceptions set forth in this Section 3.3.4.

3.3.4.2 Failure to Achieve Minimum Retention; Cure. If Customer fails to achieve the Exclusivity Minimum Retention Quantities for any Measurement Period (a "**Shortfall**"), exclusivity for the relevant Molecule/API shall lapse unless Customer cures such failure by either:

(i) [*]; or

(ii) [*] The Exclusivity Fee constitutes a pre-agreed commercial fee solely for the maintenance of exclusivity [*]. Payment of the Exclusivity Fee shall not require manufacture or supply of Products and shall be exclusive of VAT or similar indirect taxes. For the avoidance of doubt, payment of an Exclusivity Fee permits Customer to maintain exclusivity but shall not reinstate exclusivity once lost.

3.3.4.3 No Reinstatement. For the avoidance of doubt, once exclusivity for a Molecule/API is lost due to Customer's failure to meet the Exclusivity Minimum Retention Quantities (including failure to timely cure pursuant to Section 3.3.4.2), such exclusivity shall not be reinstated for the remainder of the Term.

3.3.4.4 Excused Shortfalls. Exclusivity shall remain in effect in the event that Customer's failure to meet the Exclusivity Minimum Retention Quantities for a given Post-Launch Exclusivity Year arises from (i) a Force Majeure event, (ii) Supplier's inability or failure to supply the quantity of Product in accordance with an accepted P.O. or a P.O. submitted in accordance with the Forecast and the indicative lead time, (iii) a material breach of this Agreement by Supplier, (iv) any delay caused by a Regulatory Authority (including any delay in issuing a regulatory approval), or (v) a documented safety or efficacy issue asserted by a Regulatory Authority. For purposes of calculating satisfaction of the Exclusivity Minimum Retention Quantities only, any Product ordered by Customer that is determined to be defective shall be deemed accepted, and shall count towards the Exclusivity Minimum Retention Quantities for the relevant Post-Launch Exclusivity Year.

3.3.5 Non-Retroactivity and Pre-Existing Binding Commitments.

3.3.5.1 Notwithstanding Sections 3.3.2 and 3.3.3, Customer expressly acknowledges that Supplier's exclusivity obligations under this Agreement cannot be applied retroactively to any third party with whom Supplier (or its Affiliates) entered into any agreement or other binding arrangement prior to the Effective Date ([*] (together, the "**Prior Binding Commitments**"). Supplier is authorized to [*] such Prior Binding Commitments [*] without breach of this Agreement. No provision of this Agreement shall be interpreted as restricting, impairing or conditioning Supplier's or such third parties' freedom to operate under such Prior Binding Commitments. Supplier may continue and expand [*] such Prior Binding Commitments after their expiration or termination with those same third parties [*] without notice to or consent of Customer and without breach of the exclusivity granted hereunder. For the avoidance of doubt, the expiration or termination of any Prior Binding Commitments does not give rise to exclusivity rights in favour of Customer.

3.3.5.2 Notwithstanding the foregoing: (a) [*], and (b) Supplier shall not, after the Effective Date, enter into any agreement that would permit a third party [*] to purchase Product for the Molecule/API.

3.3.6 Customer Use-Restrictions (Reserved Molecules). For the molecules listed in Schedule 2 as Reserved Molecules, Customer shall not purchase the Product for, integrate the Product with, or otherwise use the Product in combination with those molecules during the stated restriction period.

3.3.7 Competition Law; Scope. The Parties shall implement any exclusivity narrowly (by Molecule/API, optional Indication/Field, Territory, and Term) and in compliance with applicable competition/antitrust laws.

3.3.8 Remedies. A breach of this Section 3.3 may cause irreparable harm; the non-breaching Party may seek injunctive relief, without prejudice to damages and other remedies available under this Agreement.

4. CHANGES IN SPECIFICATIONS; DEVELOPMENTS

4.1 Changes in Specifications.

4.1.1 Product Specifications. The Specifications may only be modified or supplemented by mutual written agreement of the Parties.

4.1.2 Qualification of Alternative [*] Sources. The Parties may qualify a suitable alternative [*] for Products (from a second [*] supplier) to reduce the risk of disruption in supply of Products as a replacement or substitution [*] to that described in the Specifications.

4.1.3 Customer-Requested Specification Changes for Legal Compliance. Customer shall promptly inform Supplier of any proposed change in the Specifications which is necessary in order for them to conform with any applicable laws in the Territory, in which event Supplier shall promptly notify Customer in writing whether it is willing to change the Specifications and if this would result in any change in the Price of the relevant Products, such consent not to be unreasonably withheld, conditioned or delayed.

4.1.4 Regulatory-Impacting Changes. Where a proposed change (by either Party) may reasonably impact a regulatory filing or registration (e.g., material change, [*], manufacturing site), the proposing Party shall notify the other in writing, the Parties will plan and coordinate submissions (if any), and agree on timelines and cost allocation. Supplier has no liability for Customer's regulatory approvals or filing strategies; Customer remains responsible for any variations to Customer's Finished Product approvals.

4.1.5 Termination Right for Unresolved Specification Modifications. If no agreement is reached between the Parties regarding a request of modification as per Sections 4.1.3. (Customer-Requested Specification Changes for Legal Compliance) and 4.1.4. (Regulatory-Impacting Changes) above within a reasonable time, then either Party shall have the right to terminate this Agreement solely with respect to the particular Products that are the subject of the proposed modification.

4.2 Developments.

4.2.1 Intellectual Property. All intellectual property rights related to any and all Products and/or parts thereof related to but not limited to copyrights, trademarks, patents, design rights, as well as manufacturing and/or processes, technology, control processes and methods thereof, inventions, discoveries, modifications, derivatives, innovations, enhancements, improvements, know-how, trade secrets, computer programs, screen displays, adaptations, documentation, specifications, designs and all other works, articles, concepts or ideas developed, made, written, created, discovered

or designed by Supplier and/or on its behalf, its employees, agents and suppliers (including all samples, drafts, moulds, artwork, designs, film and proofs) (all together, "**Intellectual Property Rights**") shall remain the sole and exclusive property of Supplier.

4.2.2 Product Improvements. Any improvement, derivative and/or modification to the Product and/or any parts of it that is specifically developed for, or at the request of, Customer ("**Product Improvement**") shall be governed by a separate, mutually executed product development agreement, which shall address scope of work, timelines, ownership of results, and allocation of costs.

5. **PRICE**

5.1 Product Pricing and Adjustment Mechanism. The purchase price for each Product shall be as set out in Schedule 3 (for each such Product, the "**Price**"). The Price may be increased or decreased from time to time upon mutual agreement of the Parties in accordance with the pricing adjustment program set forth in Schedule 3.

5.2 Exclusions from Price. The Price is exclusive of any value added tax (VAT), or any other similar tax, duty fee, or any governmental charge.

6. **PAYMENT TERMS**

6.1 Payment Terms and Timing. Customer shall pay undisputed amounts under each invoice within the period set out in Schedule 4. No early payment discount will be offered, unless otherwise agreed in writing between the Parties.

6.2 Payment Method, No Deductions and No Set-Off by Customer. Payment shall be made to the bank account nominated in writing by Supplier and time of payment is of the essence. Customer shall pay all undisputed amounts due in full and cleared funds without any deduction or withholding, and Customer shall not be entitled to assert any credit, set-off or counterclaim against amounts due to Supplier under this Agreement or otherwise, except that Customer may apply Supplier-issued credit notes (by number and amount) against amounts then due.

6.3 Late payment.

6.3.1 In the event of late payment of an undisputed amount due by Customer, Supplier shall provide Customer with written notice of such overdue amount. If Customer fails to pay such undisputed overdue amount within [*] after receipt of such notice, Supplier shall be entitled to charge interest on the overdue amount at the rate of [*]. Such interest shall accrue on a daily basis from expiration of such [*] period until the date of actual payment, whether before or after judgment.

6.3.2 If Customer repeatedly fails to timely pay undisputed amounts, such that (i) more than [*] invoices are paid more than [*] after the due date within any [*], or (ii) any undisputed amount remains unpaid for more than [*] after receipt of written notice, then Supplier may, upon additional written notice to Customer and provided such failure is not cured within [*], exercise one or more of the following remedies, until such time as Customer is again current in its undisputed payment obligations:

(a) suspend further deliveries of Product (excluding Products required under accepted P.O.s already in manufacture); and/or

(b) require prepayment, in whole or in part, for future P.O.s.

Any exercise of the foregoing remedies shall be proportionate, applied prospectively, and shall not affect Supplier's obligation to supply Products already delivered or validly manufactured prior to such suspension.

7. **DELIVERY TERMS – IMPORT OBLIGATIONS - INSPECTION UPON DELIVERY**

7.1 Delivery Terms. Delivery terms are as set out in Schedule 4.

7.2 Each shipment shall be accompanied by a certificate of analysis (incorporating a certificate of conformance) for each lot contained in such shipment, with one copy provided at the same time to the Customer representative specified in the Quality Agreement. In addition, Supplier shall also provide Customer any export-related governmental certification customarily required by the relevant authorities.

7.3 Import Obligations and Compliance. Customer shall be responsible to Supplier for obtaining any necessary import licenses or other requisite documents and otherwise complying with any applicable laws or regulations concerning the importation of the Products, and for paying all applicable customs duties, taxes and charges in respect of the importation of the Products.

7.4 Inspection upon Delivery. Customer shall visually inspect the Products upon delivery and record specific reservations on the carrier's receipt for any visible loss/damage which might have happened during transit, with photos ("**Transit Claim(s)**") and shall use reasonable efforts to notify Supplier accordingly as soon as reasonably practicable and in any event within [*] following delivery. Transit Claims shall be pursued via the carrier by the Party bearing the risk of loss under the agreed Incoterm; the other Party shall reasonably cooperate.

8. **TITLE AND RISK**

8.1 Title. Title shall pass upon transfer of risk of loss.

8.2 Risks. Risks shall pass to the Customer as per the agreed Incoterm in Schedule 4.

9. **CONFIDENTIAL INFORMATION**

9.1 Definition of Confidential Information. Confidential information conveyed by a Party ("**Discloser**") to the other Party ("**Receiver**") including without limitation regarding prices, costs, discounts, inventions, planned and existing products (including the Products), packaging, customers, distributors, a Party's business or finances, or a Party's production methods or know-how, is confidential information ("**CI**").

9.2 Obligations of the Receiving Party. Receiver agrees not to use CI except for the purposes set forth herein or to disclose any CI except to employees, officers, directors, auditors, accountants, lawyers and consultants who agree to be bound by this confidentiality obligation, and to take reasonable commercial steps to protect the CI. Receiver shall not copy, reverse compile, reverse engineer, or otherwise duplicate the CI.

9.3 Restriction on Use of Supplier's Branding. Customer agrees that it will not use or permit others to use Supplier's logo or brand names without Supplier's prior written consent. This does not apply whenever customer use of Supplier's logo or names is required by a Regulatory Authority or law or regulation in connection with an application filed by the Customer relating to Customer's Finished Product or in the use, marketing, sale, offer for sale, import or export of the Product or Customer's Finished Product or to the extent any Supplier logo or brand name is displayed on the Product at the time of delivery.

9.4 Remedies for Breach of Confidentiality. Violation of these terms may cause irreparable harm; therefore, the non-breaching Party may be entitled to seek injunctive and other additional relief.

9.5 Exclusion from Confidential Information. CI shall not include information that is: (i) or becomes publicly available other than through a breach of this Agreement; (ii) or becomes available to Receiver from a source not known by Receiver to have a duty of confidentiality; (iii) developed by Receiver without the use of Discloser's CI; and (iv) information not under a duty of confidentiality and known by Receiver prior to the date of this Agreement.

9.6 Disclosure Required by Law. The Parties' non-disclosure obligations pursuant to this Agreement shall not apply to CI that a Receiver is required to disclose pursuant to any applicable law, subpoena, judicial action, order of the court or other governmental agency; provided, however, that the Receiver shall make all reasonable efforts to notify the Discloser in writing prior to the disclosure of such CI and allow the Discloser the opportunity to contest and avoid such disclosure at its own cost and expense, and further provided that the Receiver shall disclose only that portion of such CI that it is legally required to disclose.

9.7 Permitted Disclosures. Customer may also disclose the existence and terms of this Agreement to bona fide prospective investors, acquirers, merger partners, licensees and strategic partners, and, in each case, their respective professional advisors, solely in connection with the evaluation and negotiation of a potential investment, acquisition, corporate partnering, merger, license or similar transaction; provided, however, that any such disclosure shall be subject to a written confidentiality agreement with obligations of confidentiality at least as stringent as those set forth herein.

9.8 Public Announcements. If either Party is (a) required to issue a press release or make another public announcement to comply with applicable law as a publicly-traded company (including any filing with a governmental authority) as advised by such Party's legal counsel or (b) otherwise desires to issue a press release or make a public announcement regarding this Agreement or the subject matter hereof, the Parties shall coordinate with each other in advance of any such public announcement and the disclosing Party shall consider any timely comments of the non-disclosing Party in good faith, and, in the case of the filing of this Agreement or any other agreements or documents related thereto, such disclosing Party shall: (i) consult with the non-disclosing Party with respect to the preparation and submission of a redacted version of this Agreement in compliance with applicable law; (ii) provide copies of the disclosure to the non-disclosing party reasonably in advance under the circumstances of such filing or other disclosure; (iii) promptly notify the non-disclosing Party in writing of such requirement and any respective timing constraints; and (iv) give the non-disclosing Party reasonable time under the circumstances from the date of provision of a copy of such disclosure to comment upon and request confidential treatment for such disclosure.

10. DECLARED SHELF-LIFE - PRODUCT WARRANTY

10.1 Declared Shelf-Life. All Product supplied hereunder shall, at the time of delivery, comply with the shelf-life as validated and disclosed by Supplier as part of its technical documentation under Supplier´s standard storage and packaging conditions (the "**Product's Declared Shelf Life**"), provided that the Product's Declared Shelf Life shall in no event be less than [*]. However, Customer's Finished Product (including shelf life in Customer's packaging with Customer's formulation) is determined by Customer in its regulatory dossier and is not warranted by Supplier.

10.2 Product Warranty. Supplier warrants that on delivery the Products shall (i) be free from material defects in design, material and workmanship, (ii) conform in all material respects with the Specifications, (iii) be manufactured in compliance with all applicable laws, and (iv) be manufactured in compliance with the Registrations (the "**Product Warranty**"). Without limiting the foregoing, Supplier further represents and warrants that (a) at the time of delivery, the Product will not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act (the "**Act**"), (b) at the time of delivery, the Product will not be an article which may not, under the provisions of the Act, or any similar law of any other jurisdiction, be introduced into interstate commerce to a third party, (c) the Product and their method of manufacture do not, and will not, to the best of Supplier's knowledge, infringe any patent or trademark rights of any third party, and (d) all Product will be free and clear of all liens and encumbrances.

10.3 Product Warranty Period. The Product Warranty applies only if Customer notifies Supplier of: (i) any defect or non-conformity that is apparent on reasonable inspection within [*] after delivery; and (ii) any latent defect or non-conformity within [*] after discovery, but in all cases no later than [*] (the "**Product Warranty Period**"). The Warranty Period is independent from the Product's Declared Shelf Life, which is not a warranty. For clarity, the Product Warranty and the Product Warranty Period do not limit, exclude, or modify Supplier's obligations under applicable medical-device laws and regulations (including post-market surveillance, vigilance and field safety corrective actions), product-safety law, or statutory product-liability law, all of which apply independently of and are not time limited as set forth in this Section.

10.4 Exclusion of Supplier's Product Warranty. The Product Warranty does not apply if Customer notifies the non-conformity outside of the periods stated in the Product Warranty Period.

10.5 Remedies for Defective or Non-Conforming Products. In respect of any defective or non-conforming Products, where the Product Warranty applies, Supplier shall, at Customer's sole election, (i) repair the Products; or (ii) supply replacement Products; or (iii) grant to Customer a credit equal to the Price paid or payable by Customer for such Product, provided in each case that Customer, upon request, returns the relevant Products (unaltered) at Supplier's sole risk and expense to Supplier for inspection as soon as possible. Supplier shall, as soon as is reasonably practicable, inspect such samples. If Supplier concurs with Customer's claim, Customer may elect, in its sole discretion, the remedies set forth in this Section. If Supplier disagrees with Customer's claim and the Parties are unable to resolve their differences, then either Party may refer the matter to an independent specialized firm of international reputation agreeable to both Parties for final analysis, which shall be a final resolution of such issue, binding on both Parties and not subject to court proceedings absent fraud or manifest error. If the Product is determined to have met the warranty in Section 10.2, then [*] shall bear the cost of the independent laboratory testing pursuant to this Section 10.5. If the Product is determined not to have met such warranty, then [*] shall bear the costs of such laboratory testing and Supplier shall (at Customer's option) either replace (as soon as reasonably practicable) the defective Product without any cost to Customer or credit Customer for the amount of the Price of such quantities of Product.

10.6 Disclaimer of additional warranties. The foregoing Product Warranty, and any other warranty expressly set forth in this Agreement, is in lieu of any other warranty, whether written, oral, express or implied, including but not limited to, any warranty from hidden defects, merchantability and/or fitness for particular purpose, non-infringement, and any warranty allegedly arising from any (i) representation made or advice given by or on behalf of Supplier with respect to a Product or (ii) description of any Product or sample of Product. All other warranties, conditions or undertakings as to quality or description (howsoever made or implied) shall be excluded to the fullest extent permitted by law.

10.7 Customer's Responsibility for Medical Use and Regulatory Information. Customer shall use the Products as the device constituent of Customer's Finished Product under its sole responsibility. Customer shall inform Supplier in writing of the applicable intended medical use to enable Supplier to comply with its own quality-system and regulatory obligations. This notification does not constitute Supplier's approval of the intended use and does not expand Supplier's warranties or responsibilities.

11. RECALL

11.1 Collaboration in good faith. In the event that any governmental or regulatory authority requests or recommends any corrective action, field action or recall with respect to any Product or to any Customer's Finished Product in which the Product is incorporated, the Parties shall promptly discuss in good faith regarding the appropriate response. Regulatory-mandated corrective actions or recalls shall take precedence over any contrary instruction from Customer.

11.2 Root-cause analysis limited to the Product. Supplier shall, as soon as reasonably practicable following receipt of sufficient information from Customer, (i) perform a root-cause analysis limited to the Product as manufactured and supplied by Supplier, and (ii) provide Customer with a complete report detailing the findings and any corrective measures applicable to Supplier's manufacturing process, if any. For clarity, Supplier shall only be responsible for investigating aspects within its reasonable control, and shall not be required to assess, evaluate, or assume responsibility for potential causes arising from Customer's formulation, filling, assembly, integration into Customer's Finished Product, testing, storage, or transport or any third-party processes. Customer is solely responsible for recall decision-making, execution, communication to authorities, and notifications to healthcare providers or patients relating to Customer's Finished Product. Notwithstanding the foregoing, where the safety issue is reasonably attributable to the Product as manufactured and supplied by Supplier, Supplier shall lead the FSCA/FSN and required regulatory notifications for the Product; Customer shall cascade FSNs within its distribution chain.

11.3 Costs. To the extent the corrective action or recall is caused by Supplier's breach of its express Product Warranty under this Agreement, Supplier shall [*].

11.4 Sole responsibility of Customer. All recall-related decisions concerning Customer's Finished Product shall remain the sole responsibility of Customer. Customer shall keep Supplier promptly informed of any regulatory communications that directly relate to the Product and shall provide Supplier with all reasonably necessary information to permit an accurate investigation. No admission of fault shall be inferred from Supplier's cooperation under this Section.

12. LIABILITY

12.1 Exclusion of Indirect and Consequential Damages. Except with respect to a Party's indemnification obligations under Section 13, in no event shall either Party be liable to the other Party for any indirect, special, incidental, consequential, statutory, punitive or exemplary damages arising under or in connection with this Agreement including, without limitation, loss of business or profits or other economic losses or interruption of business, regardless of the nature of the claim or theory of recovery.

12.2 Liability Cap. Except with respect to liabilities that cannot lawfully be limited or excluded pursuant to Section 12.3., in no event shall either Party's total aggregate liability to the other Party for any and all claims, damages, losses, costs or liabilities arising out of or in connection with this Agreement (including indemnification obligations under Section 13), regardless of the nature of the claim or theory of recovery, exceed [*].

12.3 Non-Excludable Liabilities. Notwithstanding any other provision of this Agreement, no limitation or exclusion of liability shall apply in the cases in which such limitation or exclusion would be unlawful under applicable law. Notably, nothing in this Agreement shall operate to exclude or limit either Party's liability for (i) fraud or fraudulent misrepresentation; and/or (ii) wilful misconduct or gross negligence; and/or (iii) death or personal injury caused by that Party; and/or (iv) liabilities which cannot lawfully be excluded under applicable product-safety or statutory product-liability laws, and any mandatory recall, vigilance or field safety obligations. For the avoidance of doubt, all other limitations and exclusions of liability set forth in this Agreement shall remain valid and enforceable to the maximum extent permitted by applicable law.

12.4 Insurance. Each Party shall maintain, during the Term and for [*] thereafter, insurance coverage with financially sound and reputable insurers in such types and amounts as are commercially reasonable in light of such Party's obligations under this Agreement. Upon reasonable written request, each Party shall provide the other Party with certificates of insurance or other reasonable evidence of such coverage, subject to customary confidentiality restrictions.

13. INDEMNITIES FOR THIRD PARTY CLAIMS

13.1 Customer Indemnity. Customer shall defend and indemnify Supplier, its Affiliates, and their directors, officers, employees, and agents against any third party claim, loss, liability, damage, fine, penalty, cost and expense (including reasonable legal fees) arising out of or relating to (i) the development, manufacture, commercialization or exploitation of Customer's Finished Product (including any non-compliance of Customer's Finished Product with applicable laws and regulations (including labeling, PMS, PMCF, vigilance and market actions under Customer's responsibility); (ii) negligence, recklessness or willful misconduct of Customer (or its Affiliates or contractors) in the performance of its obligations hereunder; or (iii) Customer's breach of this Agreement; in each case except to the extent Supplier is obligated to indemnify Customer pursuant to Section 13.2.

13.2 Supplier Indemnity. Supplier shall defend and indemnify Customer, its Affiliates, and their directors, officers, employees, and agents against any third party claim, loss, liability, damage, fine, penalty, cost and expense (including reasonable legal fees) arising out of or relating to (i) death or personal injury, or (ii) tangible property damage, to the extent caused by a defect in the Product as delivered by Supplier and used in accordance with the instructions for use (IFU), (iii) solely a third party claim that the Product, standing alone

and as delivered by Supplier, infringes a patent, trademark or copyright in the country of delivery, (iv) the failure of a Product to meet the warranties set forth in Section 10.1, (v) any breach by Supplier of any of its representations, warranties, covenants, agreements or obligations under this Agreement, or (vi) the negligence, recklessness or willful misconduct of Supplier (or its Affiliates or contractors) in the performance of its obligations hereunder; in each case except to the extent Customer is obligated to indemnify Supplier pursuant to Section 13.1.

13.3 Procedure. The indemnified Party shall: (i) give prompt written notice of the claim (delay only relieving the indemnifying Party to the extent prejudiced); (ii) grant the indemnifying Party sole control of the defense and settlement (no settlement that admits fault or imposes non-monetary obligations on the indemnified Party without its prior written consent); and (iii) provide reasonable cooperation at the indemnifying Party's expense.

13.4 Relation to Recalls / FSCA. Field actions, recalls and vigilance obligations remain governed by Section 11 (Recall); this Section does not alter the cost allocation agreed therein.

13.5 Caps; Non-Excludable. For the avoidance of doubt, either Party's indemnification obligations shall be subject to the aggregate liability cap set forth in Section 12.2, except that no limitation applies to liabilities that cannot lawfully be limited or excluded.

14. FORCE MAJEURE

14.1 Events Constituting Force Majeure and Excused Performance. Delay in performance or failure to perform hereunder by either Party (other than obligations to make payments when due) shall be excused to the extent caused by circumstances beyond the reasonable control of the Party claiming such excuse (including without limitation, acts of God, riots, war, armed conflict, terrorist attacks, rebellion, nuclear disaster, volcanic eruptions, fires, lock-outs, strikes or other labor disputes, unusually severe weather, transportation problems, energy shortages, raw material shortages, power outages, accident, fire, explosion, flood, pandemic, epidemic, machine breakdown, inability to obtain supplies, or governmental actions) (each a "**Force Majeure**"). In such event, the Party affected will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto.

14.2 Notice Requirements. The Party claiming such circumstances shall give written notice to the other Party as soon as reasonably practicable, giving its best estimate of the expected period of delay.

14.3 Termination Rights for Prolonged Force Majeure. If a Force Majeure event continues for a period of more than [*], the non-affected Party may terminate this Agreement upon written notice to the delayed Party.

15. RECORDS – REGULATORY COMPLIANCE – AUDITS

15.1 Regulatory Status of the Devices; Roles. The regulatory status of the Product is as set forth in Schedule 1-A.

15.2 Customer's Finished Product. Customer remains solely responsible for the regulatory approval, labeling, clinical, PMS/PMCF, vigilance, and market actions of the finished drug–device combination product, including any submissions referencing Supplier's Product or DMF. This allocation aligns with MDR obligations placed on the legal manufacturer of the marketed product and FDA/OCP practice for combination products.

15.3 Information support. Upon reasonable written request, Supplier shall provide high-level summaries and standard technical statements documentation needed for Customer's conformity assessment or regulatory filings (e.g., material declarations, risk-management summaries, verification/validation summaries), subject to confidentiality and Supplier's right to redact protectable know-how, proprietary processes, or information unrelated to the Products.

15.4 Maintenance of Records. All manufacturing records with respect to the Products [*] ("**Manufacturing Records**") shall be created, maintained, and retained by Supplier in compliance with all applicable medical device laws and regulations, including, as applicable, the U.S. Federal Food, Drug, and Cosmetic Act and FDA implementing regulations (including 21 C.F.R. Parts 210, 211, and 820) and Regulation (EU) 2017/745 on medical devices (MDR), as amended from time to time. Supplier shall retain the Manufacturing Records for a period required by applicable law for medical devices following the expiry of Product for each lot of Product to which said records pertain. Supplier shall provide Customer with complete and accurate copies of the Manufacturing Records for each Product, upon Customer's request. In all cases, Supplier shall notify Customer of any intention to destroy such Manufacturing Records and shall afford Customer the opportunity to obtain such records from Supplier.

15.5 Customer Audits. During the Term, Customer may conduct [*] audit per calendar year, at a mutually agreed time during normal business hours, strictly limited to [*]. Additional [*] audits are permitted where there are [*]. All auditors must sign Supplier's confidentiality and EHS terms. Customer shall have no right to access unrelated production lines, Supplier's financial records or confidential third party or process information. Supplier shall use commercially reasonable efforts to provide a written response to any audit findings within [*] of receipt of such observations and conclusions. The Parties will discuss such response and Supplier shall promptly implement (and cause to be implemented) corrective actions which are mutually agreed and reasonably satisfactory to Customer; provided, however, that Customer may, in its sole discretion, accept Product from Supplier prior to Supplier's completion of all corrective action. Customer shall have the right to review relevant documentation in connection therewith, with the exception of Supplier´s financial records.

15.6 Debarment. Supplier agrees that in performing its obligations under this Agreement, it (and its Affiliates and subcontractors) will not be, or employ or use any person that has been, debarred under Section 306(a) or 306(b) of the Act (or the foreign equivalent thereof).

15.7 Regulatory & Notified Body Access. Supplier will cooperate with competent authority (e.g., Regulatory Authority) and Notified Body inspections insofar as they relate to the Product, including where unannounced audits are mandated under MDR; access may be limited to relevant areas and accompanied by Supplier personnel. Customer acknowledges such audits are outside Supplier's control; fees and costs charged by authorities/NBs are Supplier's for Product compliance, except where the audit arises from Customer's use, integration or Customer's Finished Product issues. Supplier shall advise Customer as soon as practicably possible of any Regulatory Authority visit that relates to a Product or the Supplier's facility(ies) where Product is manufactured, or any written or oral inquiries by such Regulatory Authority concerning the Product (including safety and efficacy claims) or any such facility. If such visit or inspection is related to the Product, Supplier shall, to the extent allowed by applicable law, allow one or more representatives of Customer to attend. To the extent allowed by applicable law, Supplier shall promptly furnish Customer [*]. Supplier shall reasonably consult with Customer regarding any communications or responses directly related to the Product.

15.8 Business Continuity Notice Obligation. Supplier shall promptly notify Customer if Supplier becomes aware of any circumstance that could reasonably threaten the continuity of supply of the Product, including: (i) regulatory enforcement actions; (ii) NB findings affecting certification; (iii) Material shortages; (iv) facility shutdown; or (v) other events affecting Supplier's ability to manufacture or release Product. Supplier shall provide periodic updates and cooperate in good faith to mitigate such interruption.

15.9 Classification Advice/ No Expanded Warranty. Nothing herein is a warranty of suitability for any particular classification or indication; such determinations remain with Customer/its regulators. Nothing in this clause shall be construed as a warranty that the Products are suitable for any particular intended purpose or drug-device combination; such assessments remain the sole responsibility of Customer.

15.10 Quality Agreement. The Parties shall enter into a separate written quality agreement (a "**Quality Agreement**") defining quality responsibilities, documentation, audits, change control, complaint handling, PMS data exchange, and other regulatory matters relating to the Product. In the event of inconsistency between this Agreement and the Quality Agreement with respect to quality or regulatory matters, the Quality Agreement shall prevail.

15.11 Quality Control Tests. Supplier shall perform such quality control tests as indicated in the Specifications and shall make the results of such quality control tests available to Customer on or before the date of delivery of the Product to Customer in accordance with Section 7.1.

15.12 Certificate of Analysis. Each certificate of analysis shall, for each lot delivered, specify the quality tests conducted, the Specifications and the test results, and shall certify that such lot of Product conforms to the Specifications (or shall list any confirmed deviations from the Specifications). The certificate of analysis shall also include the lot number, the location of manufacture and expiry date for the Product, as applicable.

15.13 Release. Supplier shall release the Product to Customer and Customer shall review and release such Product to the relevant markets in the Territory in accordance with its (or its Affiliate's or designee's, as applicable) standard practice. No Product shall be released by Supplier for delivery hereunder unless Supplier's tests show the Product meets the standards set forth in the applicable Specifications. Should any Product fail to meet the standards set forth in the applicable Specifications, Supplier shall (and Customer may, at its option), investigate the cause of such failure and promptly provide Customer with a written report summarizing the results of Supplier's investigations. Supplier is responsible for providing a copy of all Manufacturing Records for each lot of Product manufactured hereunder in support of Supplier's responsibility for final release decision, [*] in the Quality Agreement. Such documentation shall be provided to Customer with each shipment of Product.

15.14 Materials Suppliers. Notwithstanding anything to the contrary contained herein, (a) Supplier shall only obtain materials for the Product (the "**Materials**") from such suppliers as are named in the relevant regulatory approvals (the "**Vendors**") for the manufacturing of the Product hereunder, provided that Supplier may exercise its discretion in selecting and overseeing its Vendors, [*], (b) Supplier will perform [*] of its Vendors to ensure compliance with this Agreement (and Customer may accompany Supplier [*] of Vendors supplying Materials for the Product) and (c) Supplier shall prepare all certifications as to any Materials required by applicable laws or regulations, and shall provide copies thereof to Customer.

16. **RIGHT OF REFERENCE - REGISTRATION OUTSIDE THE TERRITORY OF REGISTRATION - COSTS**

16.1 Right of Reference. Subject to the terms and conditions of this Agreement, and solely for the purpose of enabling Customer to seek and maintain regulatory approvals for Customer's Finished Product that incorporates the Product as supplied by Supplier, Supplier shall provide Customer with a limited right of reference to Supplier's regulatory filings strictly to the extent required by the applicable Regulatory Authority.

16.1.1 Scope – FDA (United States). With respect to FDA submissions, Supplier shall, upon Customer's written request, issue Letters of Authorization (LoAs) permitting the FDA to reference the specific and limited portions of Supplier's Type III Drug Master File (DMF) that are required by FDA to support Customer's IND, NDA, ANDA or other applicable submission for Customer's Finished Product. Supplier shall have sole discretion over the content of the DMF and the scope of the LoA, provided that such scope is sufficient to meet FDA requirements for the device constituent of a drug–device combination product.

16.1.2 Scope – EU MDR (European Union). With respect to Regulation (EU) 2017/745 (MDR), Supplier shall make available to Customer, upon reasonable written request, appropriate technical summaries, declarations, and conformity statements relating to the Product that are necessary to support Customer's MDR obligations for its finished combination product (including Annex I GSPR evidence), without disclosure of Supplier's full technical documentation or proprietary manufacturing know-how. Supplier remains the legal manufacturer of the Product and retains ownership and control of its MDR technical documentation, Notified Body correspondence, and post-market documentation.

16.1.3 Excluded Information. The right of reference granted under this Section does not include any right to access, copy, reproduce, or disclose: (a) Supplier's full DMF or MDR technical file; (b) detailed

manufacturing processes, process parameters, methods, validations or acceptance criteria; (c) proprietary test methods or internal reports; (d) quality system documentation unrelated to the Product; or (e) Notified Body or Regulatory Authority correspondence, audit reports or observations; in each case except where explicitly required by a Regulatory Authority and then solely to the minimum extent required.

16.1.4 Method of Access; No General Copying Rights. Any right of reference shall be exercised solely through formal regulatory mechanisms, including LoAs or equivalent regulatory procedures. Customer shall not copy, reproduce, distribute, or otherwise disclose Supplier's regulatory documentation except where expressly required by a Regulatory Authority in connection with a specific submission. No rights are granted to Customer's sublicensees or third parties without Supplier's prior written consent.

16.1.5 No Expanded Regulatory or Support Obligations. Nothing in this Section shall be construed to: (a) transfer or expand Supplier's regulatory responsibilities beyond those applicable to Supplier as legal manufacturer of the Product; (b) obligate Supplier to maintain, amend, or adapt its regulatory filings for Customer's Finished Product or any indication, formulation, dosage, or use thereof; or (c) create any development, co-development, or regulatory partnership relationship. Customer remains solely responsible for the regulatory approval, maintenance, variation, and lifecycle management of Customer's Finished Product.

16.2 Registration request. At Customer's written request, Supplier will reasonably support registration of the Product in countries outside the Territory of Registration, provided that: (i) Supplier is (and remains) listed as the legal manufacturer/registration holder where required by law; and (ii) timelines are mutually agreed.

16.3 Costs; Cost Sharing; Preconditions.

16.3.1 Participation in Relevant Costs (Cost Sharing). If Customer requests Supplier to support Registration of the Product outside the Territory of Registration, Supplier may condition any such support on Customer's written confirmation of its participation in the relevant costs (the "**Cost Sharing**"). The Parties shall discuss in good faith and agree to the scope and level of Cost Sharing (e.g., percentage split and/or monetary cap) in a Registration Cost Sharing Addendum.

16.3.2 Scope of Recoverable Costs. "**Relevant costs**" include, as applicable: regulatory agent/authorized representative fees; governmental fees; type-testing; samples; translations; notarization/apostilles/legalization; courier; site inspection charges; document preparation/administration; and any non-cancellable third party charges, together with Supplier's reasonably quoted service fees for regulatory support.

16.3.3 Preconditions to Start. Supplier shall have no obligation to initiate Registration activities until (i) the Registration Cost Sharing Addendum is executed, (ii) Customer issues the corresponding purchase order(s), and (iii) Supplier receives any agreed upfront deposit or advance payment for third party/government fees.

16.3.4 No Exclusivity Implied. Cost Sharing and/or Customer's participation to relevant costs shall not grant Customer any exclusivity, territorial restriction, or supply commitment in the relevant country unless expressly agreed in a separate, duly executed exclusivity addendum.

16.3.5 Changes and Overruns. If authorities impose additional requirements or if third party/governmental fees change, Supplier will notify Customer. The Parties will agree in writing on any adjustment to the Cost Sharing before incurring material additional spend. Absent agreement within a reasonable time, Supplier may pause or cease the Registration support; Customer shall reimburse all non-cancellable costs committed up to the pause/cessation.

16.3.6 Withdrawal by Customer. If Customer withdraws its request after activities have commenced, Customer shall reimburse all non-cancellable third party/governmental fees and Supplier's earned service fees up to the effective withdrawal date, subject to any agreed cap in the Registration Cost Sharing Addendum.

16.4 Cooperation. Customer will timely provide any information reasonably required by local authorities for the Product's registration when such information pertains to Customer's Finished Product [*].

16.5 Ownership and Use. Any registration for the Product will be owned/controlled by Supplier (or its appointed agent), and Supplier may rely on such registration for other customers unless exclusivity is expressly agreed in writing.

17. REGULATORY CHANGE OF LAW / NOTIFIED BODY REQUIREMENTS

If any change in applicable laws, regulations, NB requirements, regulatory guidance, or authority expectations (including EU MDR, FDA requirements, CDSCO rules, NMPA rules) results in increased cost, burden, process changes, documentation changes, testing requirements, or facility adjustments for Supplier, the Parties shall meet in good faith to agree on commercially reasonable adjustments to timelines, pricing, responsibilities, and support obligations.

18. COMPLIANCE WITH LAWS

18.1 General Compliance. Customer represents and warrants that it shall at all times comply with all applicable laws, regulations, codes, rules, ordinances, judgments, orders and decrees (all together, the "**Laws**"). In particular, Customer agrees to comply fully with:

18.1.1 Compliance with Anti-Bribery and Anti-Corruption Laws. All applicable Laws relating to anti-bribery and anti-corruption and, more specifically, abide by the standards of conduct set forth in the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act of 2010 and any other applicable anti-corruption and/or anti-money laundering Laws (all together the "**Anti-Corruption Laws**"); and

18.1.2 Compliance with Export Control and Trade Restrictions. All relevant export Laws, trade restriction Laws of the United States, European Union and any other applicable national Laws ("**Export Laws**") in force at the relevant time. Customer shall not, in respect of the Product: (i) export, re-export, trans-ship, or otherwise transfer, directly or indirectly, in violation of Export Laws; or (ii) use the same for any purposes prohibited by the Export Laws (including, without limitation, nuclear, chemical, or biological weapons proliferation).

18.2 Customer's compliance with Applicable Regulatory Requirements.

18.2.1 Acknowledgement of Roles. Supplier is the legal manufacturer of the Product under the EU Medical Devices Regulation (MDR) and remains responsible for the Product's MDR compliance as set out in Section 15.1. Customer is solely responsible for the regulatory compliance of Customer's Finished Product(s) that use the Product (including any drug–device combination regulated as a medicinal product), including approvals/authorisations, labeling, distribution and post-market activities applicable to such Customer's Finished Product(s).

18.2.2 Drug–Device Combinations. Where Customer's product is a medicinal product that incorporates the Product as an integral delivery device, Customer shall ensure that its regulatory dossier includes evidence that the device constituent meets the MDR Annex I General Safety and Performance Requirements (e.g., a Notified Body opinion or other acceptable evidence) and shall manage lifecycle changes accordingly.

18.2.3 Device-Led Combinations with Ancillary Medicinal Substance. Where applicable law classifies a device incorporating a medicinal substance with ancillary action as a medical device, Customer shall support the notified body/authority consultations required for such substance and implement any resulting regulatory conditions in relation to Customer's Finished Product.

18.2.4 Vigilance and Field Actions Downstream. Customer shall promptly implement and cascade any Field Safety Notices (FSNs) relating to the Product within its distribution chain, cooperate in Field Safety Corrective Actions (FSCAs), and provide Supplier with downstream data reasonably needed for investigation and reporting, in each case without limiting Supplier's MDR obligations as device manufacturer.

18.2.5 No Expansion of Supplier Warranties. Nothing in this Section expands Supplier's warranties or shifts to Supplier any regulatory responsibility for Customer's Finished Product(s) beyond Supplier's MDR obligations as the legal manufacturer of the Product.

18.2.6 Supplier Cooperation. Supplier shall provide reasonable assistance and shall cooperate in good faith upon Customer's request with respect to fulfilling any of its compliance obligations with applicable regulatory requirements under this Section 18.2. Customer shall be responsible for Supplier's reasonable costs and pre-approved (in writing) out-of-pocket expenses incurred in providing such assistance.

19. INTELLECTUAL PROPERTY RIGHTS

19.1 Supplier's Ownership. Customer acknowledges and agrees that Supplier shall be the sole and exclusive owner of all Intellectual Property Rights related to any and all Products and/or parts thereof as defined above.

19.2 No Implied Rights. Nothing contained in this Agreement shall be deemed to grant either directly, by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either Party, except to the extent expressly provided for under this Agreement.

20. PRODUCT PHASE-OUT AND DISCONTINUATION

20.1 No Discontinuation of Product. Supplier acknowledges that the Product is a material and integral component of Customer's Finished Product. Accordingly, subject to Sections 20.2 through 20.4, Supplier shall not discontinue, phase out, or materially reduce the manufacture or supply of the Product during the Term.

20.2 Exceptions. Supplier may discontinue manufacture or supply of the Product only to the extent strictly required by:

a) applicable law,

b) a binding order or requirement of a Regulatory Authority or Notified Body, or

c) documented and substantiated safety concerns that render continued manufacture or supply unlawful or impracticable despite commercially reasonable mitigation efforts.

20.3 Notice. In the event a discontinuation is permitted under Section 20.2, Supplier shall give Customer as much notice as reasonably possible but, to the extent practicable, in no event less than [*] prior written notice ("**Phase-Out Notice**"). Notwithstanding the foregoing, Supplier may shorten the notice period where required by applicable Regulatory Authority or Notified Body decisions.

20.4 Discontinuation for Convenience. Supplier may, at its discretion and upon no less than [*] prior written notice, discontinue the manufacture of Product.

20.5 Supplier's Obligations During Phase-Out Period. During the phase-out period, Supplier shall:

a) continue supplying the Product under the terms of this Agreement;

b) offer Customer a last-time-buy opportunity, enabling Customer to place P.O.s in excess of the quantity forecasted for each month for delivery during the notice period; and

c) maintain the Product specifications unchanged, unless required by applicable law, safety concerns, or Material unavailability.

20.6 Efforts to avoid Supply Disruption. Supplier shall use commercially reasonable efforts to fulfil all last-time buy P.O.s and avoid supply disruptions due to end-of-life of Materials and shall promptly notify Customer if such circumstances arise.

20.7 Discontinuation License. Subject to Sections 20.1-20.6 and only if supply disruption is based on Supplier's decision to discontinue the Product during the Term of this Agreement, Customer and Supplier shall discuss in good faith [*], subject to commercially reasonable terms and conditions to be mutually agreed upon by the Parties. Such license shall not survive end of the term of the Agreement, unless otherwise agreed in writing.

20.8 Emergency Transfer License. Subject to the terms of this Section 20.8, Supplier grants to Customer [*] ("**Necessary IP**") [*] solely to ensure continuity of supply of the Customer's Finished Product to patients [*], excluding any period impacted by [*] or predominantly caused by [*] (the "**Transfer License**"). In the event the requirements for the Transfer License are met, and Customer [*] a royalty will be paid by [*]. The royalty amount so calculated will be paid by Customer to Supplier on annual basis, against regular invoice issued by Supplier on 31st January of each year. [*]. However, Customer shall use reasonable efforts to return to Supplier supply and not use the license after Supplier resumes supply.

In this case, the disclosure of [*] shall be discussed and governed by the Confidentiality provisions of this Agreement.

20.9 No Obligation Beyond Phase-Out Period. Nothing in this clause obliges Supplier to continue manufacturing the Product beyond the phase-out period, except for quantities validly ordered under the last-time-buy process.

20.10 Acknowledgement. Supplier acknowledges and agrees that it may only discontinue the Product pursuant to this Section 20 in the event that it fully and permanently discontinues the Product and ceases manufacture and supply of the Product for itself, its Affiliates and all third parties.

21. **TERM - TERMINATION - CONSEQUENCES OF TERMINATION**

21.1 Term. Unless earlier terminated in accordance with the provisions of this Agreement, this Agreement shall enter into force on the Effective Date and shall continue for an initial term ending [*] (the "**Initial Term**"). Upon expiry of the Initial Term, this Agreement shall automatically continue in force for an indefinite duration, unless and until terminated by either Party in accordance with Section 21.3. (the "**Extended Term**" and, together with the Initial Term, the "**Term**"). Following the expiry of the Initial Term, Supplier may terminate this Agreement for any reason (or no reason) upon not less than [*] prior written notice to Customer (which notice may only be delivered following expiry of the Initial Term). For the avoidance of doubt, the continuation of this Agreement on an indefinite basis, the grant or maintenance of any exclusivity, the inclusion of Exclusivity Minimum Retention Quantities for future periods, or Customer's compliance with such quantities shall not be construed as extending the Term of this Agreement or limiting either Party's right to terminate this Agreement in accordance with Section 21.

21.2 Termination by Supplier. Supplier may terminate this Agreement:

21.2.1 upon written notice to Customer if Customer breaches any undisputed payment obligations and does not cure such breach within [*] after receipt of written notice of such breach from Supplier; or

21.2.2 following discontinuation of the Product, subject to the discontinuation procedures and terms set forth above.

21.3 Termination by Customer. Customer may terminate this Agreement:

21.3.1 upon [*] prior written notice to Supplier, for any reason (or no reason) at any time during the Term;

21.3.2 upon written notice to Supplier if Supplier breaches any provision of this Agreement and does not cure such breach within [*] after receipt of a written notice of such breach from Customer.

21.4 Termination by either Party. Either Party may at any time terminate this Agreement by giving written notice to the other if the other Party goes into liquidation, becomes bankrupt, makes a voluntary arrangement with its creditors or has a receiver or administrator appointed or any comparable event of insolvency.

21.5 Accrued Rights. The termination of this Agreement for any reason shall not affect either Party's accrued right, remedies or liabilities including any payment of any sum due by Customer at the effective date of termination and/or Customer's obligation to take delivery of and pay the Price of the Products ordered before the effective date of termination.

21.6 Effects of Termination. Upon expiration or termination of this Agreement, Customer shall have the option (in its discretion) of either (i) cancelling all outstanding P.O.s or (ii) requiring Supplier to continue to supply the Product in accordance with all P.O.s previously submitted (which supply shall be in accordance with the terms and conditions of this Agreement). In the event that Customer exercises its option to continue to receive Product pursuant to the foregoing sub-clause (ii), then Supplier shall manufacture and supply to Customer the applicable Product in such P.O.s in accordance with the terms and conditions of this Agreement. In addition, in the event of termination by Supplier pursuant to Section 21.2.2, the terms of Section [20.7] shall apply.

22. GOVERNING LAW AND JURISDICTION

22.1 Governing Law. The construction, validity and performance of this Agreement and any dispute or claim arising out of or in connection thereof (including non-contractual disputes or claims) shall be governed by and construed in accordance with the substantive laws of Switzerland, excluding its conflict-of-laws rules and the United Nations Convention on Contracts for the International Sale of Goods (CISG).

22.2 Jurisdiction. The courts of Zurich, Switzerland (City of Zurich, 1st District) shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including non-contractual disputes or claim).

23. MISCELLANEOUS

23.1 Survival. The terms, provisions, representations and warranties contained in this Agreement that by their sense and context are intended to survive the performance thereof (including Sections 4.2, 7.4, 10.1 through 10.6, 15.4, 15.5, 15.7, 21.5, and 21.6, and Articles 1 (solely to the extent necessary to interpret surviving provisions), 8, 9, 11, 12, 13, 16, 19, 22, and this 23) by either Party or both Parties hereunder shall so survive the completion of performance, expiration or termination of this Agreement.

23.2 Mutual Representations and Warranties.

23.2.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that:

a) neither the execution nor performance of this Agreement violates any other contract or obligation of such Party;

b) it is validly created and currently in existence or good standing in its state of incorporation;

c) its signatory is authorized and fully empowered to execute this Agreement on its behalf; and

d) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity).

23.2.2 Supplier Representations and Warranties. Supplier represents and warrants to Customer that:

a) it has the requisite Intellectual Property Rights in its equipment, facility(ies) and technologies to manufacture and supply the Product in accordance with this Agreement

b) it has not misappropriated, and will not misappropriate, any Intellectual Property Rights of any third party in performing its obligations under this Agreement.

c) to the extent Supplier's intellectual property is concerned, no claims have been asserted, or, to Supplier's knowledge, threatened by any third party, nor are there any valid grounds for any claim of any such kind to the effect that the use, manufacturing, distribution, offer for sale, sale, importing or exporting of the Product infringes or will infringe on any intellectual property rights of any third party;

d) it has and will continue to have all permits, licenses, certifications, authorization and other approvals necessary for it to perform its obligations under this Agreement; and

e) all tangible information and data provided by or on behalf of Supplier to Customer on or before the Effective Date in contemplation of this Agreement was and is true, accurate and complete in all material respects, and Supplier has not failed to disclose, or cause to be disclosed, any information or data that would cause the information and data that has been disclosed to be misleading in any material respect.

23.3 Assignment. This Agreement may not be assigned by either Party, in whole or in part, without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned, or delayed; except that (i) either Party may, without the written consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party and (ii) Customer may, without the written consent of Supplier, assign this Agreement and its rights and obligations hereunder (or under a transaction under which this Agreement is assumed) in connection with the transfer or sale of all or substantially all of its assets or business related to the subject matter of this Agreement, or in the event of its merger or consolidation or similar transaction. Any assignment by Supplier that would result in a change to the approved manufacturing site, the manufacturing legal entity, or any other element that is part of the regulatory filing or approval for the Product or Customer's Finished Product shall require Customer's prior written approval. Any attempted assignment not in accordance with this Section 23.3 shall be void.

23.4 No Waiver. No delay or omission by either Party hereto in exercising any right or power hereunder will impair such right or power or be construed to be a waiver thereof. A waiver by either Party hereto of any of the covenants to be performed by the other or any breach thereof will not be construed to be a waiver of any succeeding breach thereof or of any other covenant herein contained.

23.5 Entire Agreement, Amendment. This Agreement, including the Schedules attached hereto, together with the Quality Agreement constitutes the entire contract between the Parties as to the subject matter contained and terminates and supersedes any prior written or unwritten understanding relating to same, except that any validly executed confidentiality agreement shall remain in full force and effect for the remaining term thereunder. Article, section, and paragraph headings, if any, are inserted for convenience only and shall not add to or detract from this Agreement. This Agreement may be altered or amended only by a written document signed by both parties.

23.6 Severability. If any provision of this Agreement is held invalid by any tribunal in a final decision, such provision shall be deemed modified to eliminate the invalid element, and, as so modified, such provision shall be deemed a part of this Agreement. If it is not possible to modify any such provision to eliminate the invalid element, such provision shall be deemed eliminated from this Agreement. The invalidity of any provision of this Agreement shall not affect the force and validity of the remaining provisions.

23.7 Notices. All notices required by this Agreement shall be in writing and shall be deemed given as of the date received and shall be personally delivered or sent either by registered or certified mail, return receipt requested, or by nationally recognized overnight courier, addressed to the Parties at the addresses specified in Schedule 4.

23.8 Attorney's Fees and Other Costs. In the event of any controversy, claim or dispute between the Parties hereto arising out of a breach of this Agreement or otherwise relating to this Agreement, the prevailing Party shall be entitled to recover from the losing Party reasonable attorney's and experts' fees and other costs reasonably incurred by the prevailing Party in enforcing its rights under this Agreement.

23.9 Third Party Beneficiaries: There shall be no third party beneficiaries of this Agreement unless the Parties specifically identify such beneficiaries in writing.

23.10 Order of Precedence: Any inconsistency in any documents relating to the purchase of the Product shall be resolved by giving precedence in the following order: (i) the terms and conditions of this Agreement (including the Schedules attached hereto); (ii) the provisions and text appearing on the acceptance of a P.O.; and (iii) other documents, exhibits and attachments which accompany the Products. Notwithstanding the foregoing, the Quality Agreement shall prevail over this Agreement solely with respect to quality and regulatory matters.

23.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under applicable law.

23.12 Electronic Signature. This Agreement (and any orders, statements of work, addenda, notices and other documents relating to it) may be executed and delivered electronically, including by click-to-accept, typed name, scanned/PDF signatures, or digital signatures applied through a reputable e-signature platform. Each such electronic signature constitutes the signatory's intent to sign and shall have the same legal effect as a handwritten signature to the fullest extent permitted by applicable law. This Agreement may be signed in counterparts, each of which is deemed an original, and together they constitute one instrument. Electronic records generated by the e-signature service (including audit trails and certificates) are admissible as original evidence of execution and delivery. The foregoing is without prejudice to documents that mandatorily require notarization, public form or filing in a public register under applicable law, which are excluded unless executed in the form legally required.

On behalf of PLASTIAPE S.P.A.

/s/ Alfredo Masuello

Signature:
Name: Alfredo Masuello
Title: Managing Director

On behalf of ORPHAI THERAPEUTICS, INC.

/s/ Paul Boni

Signature:
Name: Paul Boni
Title: Chief Financial Officer

SCHEDULE 1
PRODUCT & SPECIFICATIONS

[*]

SCHEDULE 1-A
REGULATORY OVERVIEW – NON-BINDING

[*]

SCHEDULE 2
EXCLUSIVITY & INDICATION-SPECIFIC RESTRICTIONS

[*]

SCHEDULE 3
PRICE – PRICE ADJUSTMENT

[*]

SCHEDULE 4

OTHER COMMERCIAL AND OPERATIONAL TERMS

[*]

Exhibit 31.1

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

I, Dirk Thye, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc. for the quarter ended June 30, 2026;

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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: August 14, 2026

/s/ Dirk Thye

Dirk Thye

Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Brendan Hannah, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc. for the quarter ended June 30, 2026;

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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: August 14, 2026

/s/ Brendan Hannah

Brendan Hannah

Chief Business Officer, Chief Operating Officer, and Chief Compliance Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof to which this Certification is attached as Exhibit 32.1 (the "Report"), I certify, pursuant to Rule 13a-149b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 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 Exchange Act; 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: August 14, 2026

By: /s/ Dirk Thye

Dirk Thye

Chief Executive Officer and Chief Medical Officer

(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof to which this Certification is attached as Exhibit 32.2 (the "Report"), I certify, pursuant to Rule 13a-149b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 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 Exchange Act; 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: August 14, 2026

By: /s/ Brendan Hannah

Brendan Hannah

Chief Business Officer, Chief Operating Officer, and Chief Compliance Officer

(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.