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

FORM 8-K/A
Amendment No. 2

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 17, 2026

QUINCE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-38890	90-1024039
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

611 Gateway Boulevard, Suite 273 **South San Francisco, California** **(Address of principal executive offices)**	**94080** **(Zip Code)**

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13d-4(c))

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**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Explanatory Note

This Amendment No. 2 on Form 8-K/A (this "Amendment No. 2") amends the Current Report on Form 8-K filed by Quince Therapeutics, Inc. (the "Company") with the Securities and Exchange Commission (the "SEC") on May 18, 2026 (the "Original Filing"), as amended by Amendment No. 1 to the Original Filing, filed by the Company with the SEC on May 18, 2026, in which the Company reported, among other events, the completion of the acquisition of Orphai Therapeutics, LLC, a Delaware limited liability company (formerly Orphai Therapeutics, Inc., a Delaware corporation) ("Orphai Subsidiary") and Orphai Holdings Therapeutics, Inc. ("HoldCo"). This Amendment No. 2 is filed to (i) update the information in Item 9.01(a) of the Original Report to include the audited financial statements of Orphai as of and for the years ended December 31, 2025 and 2024 and the unaudited interim condensed consolidated financial statements of Orphai as of and for the three months ended March 31, 2026 and 2025; and (ii) update the information in Item 9.01(b) of the Original Report to include the unaudited pro forma condensed consolidated financial information of the Company as of and for the three months ended March 31, 2026 and the year ended December 31, 2025. The financial statements have been presented for Orphai, which was the entity that held all of the assets acquired. None of the assets acquired were attributable to HoldCo. Additionally, this Amendment No. 2 is filed to incorporate by reference business and risk factor information of Orphai. This Amendment No. 2 does not amend any other item of the Original Report.

Capitalized terms used but not defined herein have the meanings given to them in the Original Report.

In accordance with Rule 12b-15 of the Securities Exchange Act of 1934, as amended, the complete text of Item 9.01 (as amended) is included herein.

Item 8.01. Other Events

The information set forth in the "Business Section of the Company" reflecting the business of the Company following the acquisition of Orphai is attached hereto as Exhibit 99.4 and incorporated herein by reference.

The information regarding the risks associated with the business and operations of the Company following the acquisition of Orphai set forth in the "Risk Factors of the Company" is attached hereto as Exhibit 99.5 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(a) Financial statements of business acquired

The audited financial statements of Orphai as of and for the years ended December 31, 2025 and 2024 and the related notes thereto are attached hereto as Exhibit 99.6 and incorporated herein by reference.

The unaudited interim condensed consolidated financial statements of Orphai as of and for the three months ended March 31, 2026 and 2025 and the related notes thereto are attached hereto as Exhibit 99.7 and incorporated herein by reference.

(b) Pro forma financial information

The unaudited pro forma condensed combined financial information of the Company as of and for the three months ended March 31, 2026 and the year ended December 31, 2025 is attached hereto as Exhibit 99.8 and incorporated herein by reference.

(d) Exhibits

Exhibit Number	Description
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. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
3.1	Certificate of Designation of Series C Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
4.1	Form of Warrant to Purchase Series C Non-Voting Convertible Preferred Stock or Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
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 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
10.2*	Form of Registration Rights Agreement, by and among Quince Therapeutics, Inc. and certain investors signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
10.3	Employment Letter between the Company and Brigette Roberts, effective May 18, 2026 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
10.4	Employment Letter between Orphai Therapeutics Inc. and Brigette Roberts, effective May 12, 2026 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the Securities and Exchange Commission on May 18, 2026).
10.5	Retention Bonus Agreement dated May 17, 2026 between the Company and Dirk Thye (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
10.6	Retention Bonus Agreement dated May 17, 2026 between the Company and Brendan Hannah (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
23.1	Consent of Deloitte & Touche, LLP, Independent Registered Public Accounting Firm.
99.1	Press Release issued on May 18, 2026 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
99.2	Press Release issued on May 18, 2026 (incorporated by reference to Exhibit 99.2 to the Company's Amendment No. 1 to Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
99.3	Investor Presentation, dated May 18, 2026 (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K (File No. 001-38890), filed with the SEC on May 18, 2026).
99.4	Business Section of the Company
99.5	Risk Factors of the Company
99.6	Audited Financial Statements of Orphai Therapeutics, Inc. as of and for the year ended December 31, 2025 and 2024 and the related notes thereto.
99.7	Unaudited Interim Condensed Consolidated Financial Statements of Orphai Therapeutics, Inc. as of and for the three months ended March 31, 2026 and 2025 and the related notes
99.8	Unaudited Pro Forma Condensed Combined Financial Information of the Company as of and for the three months ended March 31, 2026 and the year ended December 31, 2025

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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.

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 hereunto duly authorized.

Quince Therapeutics, Inc.

By: /s/ Dirk Thye
Name: Dirk Thye
Title: Chief Executive Officer

Date: July 29, 2026

Exhibit 23.1

We consent to the incorporation by reference in Registration Statement Form S-3 (No. 333-283897 and 333-288971) and Form S-8 (Nos. 333-231307, 333-237199, 333-253743, 333-263186, 333-265109, 333-270577, 333-278440, 333-286063, and 333-295164) of Quince Therapeutics, Inc., of our report dated July 29, 2026, relating to the financial statements of Orphai Therapeutics, Inc. appearing in this Current Report on Form 8-K dated July 29, 2026.

/s/ Deloitte & Touche LLP

Hartford, Connecticut

July 29, 2026

BUSINESS

Our Company

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, a clinical-stage biopharmaceutical company developing therapies to treat serious, underserved pulmonary disorders. 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 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. In connection with the acquisition, we received $115 million in upfront gross proceeds, with the potential to receive up to an additional approximately $72 million in gross proceeds upon the exercise of certain warrants (with an additional up to $11 million in gross proceeds available upon the exercise of warrants issued to former Orphai stockholders), in a private placement transaction from a broad syndicate of investors including Balyasny Asset Management, Affinity Asset Advisors, LLC, Coastlands Capital, Columbia Threadneedle Investments, Cormorant Asset Management, Eventide Asset Management, Foresite Capital, Janus Henderson Investors, LifeSci Venture Partners, Logos Capital, Perceptive Advisors, SilverArc Capital and Woodline Partners LP.

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 ("PAH") as well as patients with PH-ILD, LAM-001 achieved consistent, clinically relevant improvement across multiple established endpoints, including pulmonary vascular resistance ("PVR"), six-minute walking distance ("6MWD") and functional class rankings. 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 ("SAPH") in late 2026, with data expected in the fourth quarter of 2028.

Prior to the acquisition, Orphai was led by Brigette Roberts, M.D., who joined Orphai in 2021 and has played an instrumental role in the development of LAM-001 and continues to lead our company as our Chief Corporate Affairs Officer and member of our board of directors. Previously, Dr. Roberts spent approximately 15 years as a healthcare investor and portfolio manager, including at Third Point LLC, a New York based hedge fund. As part of the acquisition, Orphai's former Chief Operating Officer, Keith Fandrick, Ph.D., MBA, RAC, joined our company to oversee our operations, manufacturing and regulatory strategy as our Head of Technical Operations. Before joining us, Dr. Fandrick was a group leader in the chemical development group of Boehringer Ingelheim and former SAB member for Drug Farm.

Rapamycin, sold under the brand name Rapamune®, was first approved in 1999 by the United States Food and Drug Administration ("FDA") to prevent organ rejection in patients receiving a kidney transplant. Rapamycin inhibits the highly conserved mTOR signaling pathway, which plays a central role in the regulation of cell growth, proliferation and survival. Rapamycin was first approved as an oral liquid solution and in tablet form. It has also been approved as an intravenous injection and in a topical formulation. Rapamycin has not been approved as an inhaled formulation.

Orally administered rapamycin received FDA approval in 2015 to treat lymphangioleiomyomatosis ("LAM"), a rare lung disease caused by the proliferation of abnormal smooth muscle-like cells, which results in cystic lung destruction and pronounced airflow obstruction. A key driver of LAM is dysfunctional mTOR activation. Systemic exposure to rapamycin, however, is burdened with adverse side effects, 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 (PML), 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 [BOOP], 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 (LDH); headache; dizziness; fever; pain; abdominal pain; constipation; diarrhea; nausea; stomatitis; acne; rash; exfoliative dermatitis; abnormal/impaired wound healing. Clinical use of oral rapamycin has been further complicated by poor aqueous solubility, first-pass metabolism in the liver, and low bioavailability. As such, the concentration of drug in the blood stream varies significantly, requiring frequent plasma monitoring and dose adjustments.

Our Pipeline

LAM-001, our lead product candidate for the treatment of serious, underserved pulmonary diseases, is a proprietary inhaled dry powder formulation of rapamycin. We believe the use of an inhaled formulation may provide numerous clinical advantages and may allow us to circumvent many of the issues associated with rapamycin's systemic delivery. Targeted delivery of rapamycin directly to the lungs is designed to enable higher localized drug exposure while minimizing the drug's systemic burden, potentially enhancing its tolerability. We believe the once-daily, fixed dosed administration of LAM-001 has the potential to bolster convenience and ease-of-use for improved patient compliance.

Our lead indication for LAM-001 is PH-ILD, a disorder that collectively affects an estimated 200,000 patients in the US and Europe. Pulmonary arterial smooth muscle cell proliferation and endothelial cell dysfunction, which result in a thickening and narrowing of the pulmonary vasculature, is a primary characteristic of PH. When PH occurs in the setting of underlying ILD, it is associated with accelerated morbidity and mortality. PH-ILD has a five-year survival rate of 23%, which is worse than patients diagnosed with either PH (five-year survival rate of 54%) or ILD (five-year survival rate of 54%) alone. Patients diagnosed with PH and idiopathic pulmonary fibrosis, a particularly aggressive form of PH-ILD, have an estimated mean survival rate of just 2 years. Other than lung transplantation, there is no known cure for PH-ILD. The only therapeutic currently approved by the FDA to treat PH-ILD is inhaled treprostinil, a pulmonary vasodilator that requires three to five administrations daily. In a post-hoc analysis of the INCREASE trial and its open-label extension in PH-ILD patients, inhaled treprostinil was found to have a 38% and 74% reduction in risk of mortality compared to placebo, under two different models of survival –the inverse probability of censoring weighting model and the rank-preserving structural failure time model – respectively. However, even with treprostinil treatment, PH-ILD is characterized by continued disease progression and death, with a mean time to death in the same post hoc analysis of the INCREASE trial of 58.5 weeks for treprostinil treated patients (vs 43.5 weeks for placebo treated patients).

We initiated a multicenter, single-arm, open label exploratory Phase 2a clinical trial of LAM-001 as an add-on therapy in ten adult patients diagnosed with either PAH or PH-ILD. Patients in the trial were administered 100 μg of LAM-001 through a dry powder inhaler ("DPI") once daily for 24 weeks. In the trial, LAM-001 achieved consistent, clinically relevant improvements across multiple endpoints, including notable reduction in mean pulmonary vascular resistance (PVR) and increase in six-minute walk distance (6MWD). Further evidence of the potential clinical benefit provided by LAM-001 was documented by functional class improvement observed during the trial period, with all six trial participants who completed the trial exhibiting functional class improvement from Class III to Class II. LAM-001 was generally well tolerated with no dose interruptions due to adverse events, no drug related serious adverse events, and no trial discontinuations for reasons related to the drug candidate. Following the positive results from the Phase 2a clinical trial, we initiated a 75 patient Phase 2b trial for the evaluation of LAM-001 as a novel, disease-modifying treatment for adults with PH-ILD.

LAM-001 is also being evaluated in an ongoing investigator sponsored 19-patient, 48-week, double-blind, placebo-controlled Phase 2 trial as a treatment for BOS. BOS is an irreversible lung disease characterized by the scarring and narrowing of the bronchioles, leading to lung function deterioration and graft failure. T-cell proliferation and the related inflammatory sequelae are believed to be significant drivers of the disease. BOS is the leading cause of death in lung transplant patients, and nearly all lung transplant patients will get BOS, with only 11% of lung transplant patients alive and free from BOS ten years after lung transplant. Disease progression is rapid with a median survival of 2.5 years post the onset of BOS in lung transplant recipients. Other than a replacement transplant, there is no cure, and no therapeutic agent has received approval by the FDA for the treatment of BOS. The estimated BOS patient population in the US and Europe combined will be approximately 30,000 by 2032.

Standard treatment for BOS consists of long-term off-label immunosuppressive regimens that combine a calcineurin inhibitor, a cell cycle inhibitor and corticosteroids. Patients may also be administered fluticasone, oral montelukast and azithromycin (FAM) triple therapy. An alternate therapeutic combination replaces the cell cycle inhibitor with an oral mTOR inhibitor or adds an oral mTOR inhibitor to the regimen.

In the context of BOS, we believe mTOR inhibition with rapamycin may provide multifaceted benefit by suppressing not only adaptive immune responses but also fibroproliferative processes characteristic of obliterative bronchiolitis. Specifically, rapamycin inhibits effector T-cell differentiation and proliferation while promoting regulatory T cells (Tregs), reduces B-cell activation and antibody production (potentially mitigating antibody-mediated components of chronic rejection), and limits fibroblast proliferation, myofibroblast differentiation, and extracellular matrix deposition in the airways. It may also attenuate vascular smooth muscle cell hyperplasia, angiogenesis, and epithelial-mesenchymal transition that contribute to airway obliteration and remodeling. These effects collectively target the chronic alloimmune inflammation and dysregulated repair mechanisms driving progressive FEV1 decline in BOS.

Oral rapamycin has been shown in small studies to have a beneficial impact on both the treatment of progressive BOS, showing stabilization of lung function. However, tolerability remains challenging given the numerous adverse events ("AEs") associated with orally delivered rapamycin, including increased susceptibility to infection, lymphoma and malignancy: 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 (PML), Latent viral infection reactivation, Basal cell carcinoma, Squamous cell carcinoma, Melanoma, Lymphoma; 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 (ILD); Non-infectious pneumonitis; Bronchial anastomotic dehiscence; Increased creatinine; Decline in renal function; Proteinuria; Hypercholesterolemia: Hypertriglyceridemia, Hyperlipidemia; Diabetes mellitus; Hypokalemia; Anemia; Leukopenia; Neutropenia; Thrombocytopenia; Pancytopenia; Arthralgia; Myalgia; Bone necrosis; Hepatotoxicity (including fatal hepatic necrosis); Hepatic artery thrombosis; Lymphocele; Lymphedema; Ovarian cysts; Menstrual disorders (including amenorrhea, menorrhagia); Increased lactate dehydrogenase (LDH); Headache; Dizziness; Fever; Pain; Abdominal pain; Constipation; Diarrhea; Nausea; Stomatitis; Acne; Rash; Exfoliative dermatitis; Abnormal/impaired wound healing.

In a single-center study conducted by Dr. Stuckey at the University of Michigan in 49 patients administered oral rapamycin post lung transplant, 55% discontinued therapy due to adverse events including fatigue, edema, pneumonitis, and renal dysfunction. In addition, because of its low and variable oral bioavailability, rapamycin requires frequent plasma monitoring and dose adjustments to achieve target concentrations. We believe that the minimization of systemic toxicities through the use of an inhaled formulation of rapamycin may address tolerability issues while also enabling targeted drug delivery with higher local exposure. Additionally, we believe the once-daily, fixed dosed administration of LAM-001 has the potential to bolster convenience and ease-of-use for improved patient compliance. The Phase 2 BOS trial is fully enrolled with preliminary data expected to be available in the first quarter of 2027. LAM-001 has been granted Orphan Drug Designation in the United States and in the European Union for the treatment of BOS.

We are also planning to study LAM-001 for the treatment of SAPH. Sarcoidosis is a systemic inflammatory condition characterized by the formation of granulomas. While sarcoidosis can affect various organs and tissues, the lungs and pulmonary function are impacted in 90% of cases. The origin of sarcoidosis remains unknown.

SAPH, categorized within Group 5 PH, is an uncommon complication that affects an estimated 15% of patients with pulmonary sarcoidosis, and is associated with increased morbidity and mortality. With a five-year survival rate of 55%, SAPH has an 8 to 10 times higher mortality rate than pulmonary sarcoidosis alone. The incidence of SAPH in patients with pulmonary sarcoidosis is estimated to be between 6% and 28%, with the prevalence in pulmonary sarcoidosis patients awaiting lung transplants as high as 74%. There are collectively an estimated 60,000 patients with SAPH in the US and Europe.

There are no FDA-approved therapies for SAPH. Therapeutics used to treat pulmonary arterial hypertension (PAH), including sildenafil, prostacyclins and endothelin receptor antagonists (ERA), are commonly used off label but with limited benefit. Approximately 22% of SAPH patients receive no PH specific therapy.

We believe scientific and clinical observations involving sarcoidosis provide compelling support for the potential therapeutic utility of DPI rapamycin to treat SAPH. mTOR activation is commonly seen in granulomas of patients across different tissues and has been shown to induce sarcoidosis-like granulomas in a mouse model. In addition, the one participant with pulmonary sarcoidosis included in our Phase 2a clinical trial demonstrated significant improvement after administration of LAM-001, including a 162 meter improvement in the 6MWD score at the Week 24 trial completion, a 41% and 66% improvement in the PVR resting and peak exercise tests, respectively, and a 7% improvement in VO_2 Max. As such, we expect to initiate a Phase 2 trial specifically to assess its use as a treatment for SAPH in late 2026.

Our Strategy

We intend to establish ourselves as a leading company developing treatments for serious, underserved pulmonary diseases. To accomplish this objective, we intend to:

* *Advance the clinical development of LAM-001 as a therapeutic for patients with PH-ILD.*

A 75-patient Phase 2b trial in patients with PH-ILD is ongoing, with data expected in the first quarter of 2028.

* *Continue the ongoing clinical development of LAM-001 as a treatment for BOS.*

The use of LAM-001 as a treatment for patients with BOS is currently being evaluated in an ongoing, 48-week investigator sponsored Phase 2 trial. Full enrollment was achieved in this trial in January 2026 and preliminary results are expected to be available in the first quarter of 2027.

* *Advance the clinical development of LAM-001 as a therapeutic for patients with SAPH.*

We expect to initiate a Phase 2 trial to evaluate the use of LAM-001 as a treatment for SAPH in late 2026, with data expected in the fourth quarter of 2028.

* *Utilize the 505(b)(2) regulatory pathway to potentially expedite LAM-001 clinical development.*

We intend to pursue LAM-001 clinical development under the 505(b)(2) regulatory pathway, which may provide a streamlined, capital efficient pathway when compared to traditional drug development because it allows us to leverage the FDA's prior conclusions of safety and effectiveness for rapamycin. There can be no guarantee that we will be able to utilize such a regulatory pathway or that it would lead to a faster development, regulatory review or approval process or increase the likelihood of marketing approval.

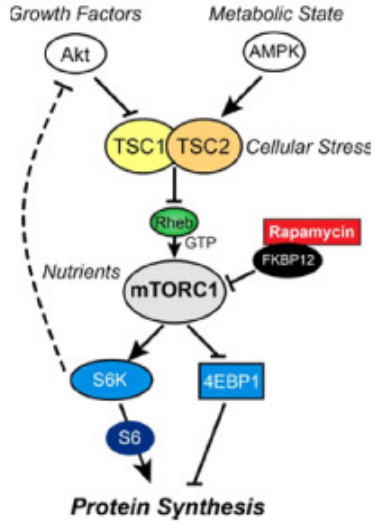
* *Pursue additional disease indications where LAM-001 may offer therapeutic advantages.*

The mTOR signaling pathway plays a critical role in the regulation of cell growth, proliferation and survival, and its dysfunctional activity is involved in a host of disease indications. Yet, the clinical use of oral rapamycin has been complicated by poor aqueous solubility, first-pass metabolism in the liver, low bioavailability, and numerous safety risks. LAM-001 has been formulated specifically to address the issues associated with oral rapamycin in pulmonary disorders where errant mTOR activity has been implicated. In addition to PH-ILD, BOS and SAPH, we continue to evaluate LAM-001 in other indications for potential future development.

Rapamycin and the mTOR signaling pathway

Rapamycin, also referred to as sirolimus and sold under the brand name Rapamune®, is a macrolide lactam that has broad immunosuppressant and antiproliferative properties related to its ability to inhibit the highly conserved serine-threonine protein kinase mTOR signaling pathway, which plays a central role in the regulation of cell growth, proliferation and survival. Fundamental to its mechanism of action is its targeting of cytosolic-FK binding protein 12 ("FKBP12") to generate an FKBP12-rapamycin complex that binds directly to the FKBP12-rapamycin binding domain of mTOR, blocking mTOR phosphorylation of downstream substrates through allosteric inhibition. Dysfunctional mTOR activation has been implicated in multiple inflammatory, proliferative and fibrotic diseases. The schematic presented below illustrates the inhibitory activity of rapamycin on the mTOR pathway.

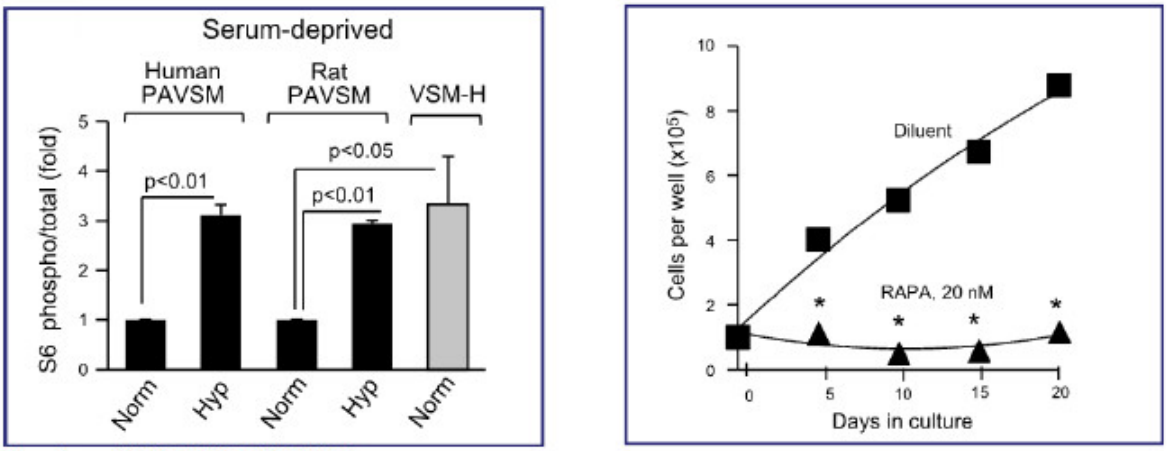
Rapamycin complexes with FKBP12 to allosterically inhibit mTOR activity.



Rapamycin was first approved as an oral solution by the FDA in 1999 to prevent organ rejection in adolescent and adult patients receiving a kidney transplant. Rapamycin was subsequently approved as an intravenous injection to treat locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumour, a rare cancer, as a topical formulation to treat facial angiofibroma with tuberous complex and as a coating for coronary stents to prevent restenosis.

In 2015, orally administered rapamycin received FDA approval to treat lymphangioleiomyomatosis ("LAM"), a rare disease that affects the lungs, kidneys and lymphatic system. LAM is caused by the proliferation of abnormal smooth muscle-like cells, which are referred to as LAM cells, which results in cystic lung destruction, airflow obstruction and impaired lymphatic drainage. As is evident in the data presented below conducted in an *in vitro* hypoxia-stimulated model of mTOR activation in both human and rodent pulmonary arterial vascular smooth muscle cells, rapamycin demonstrated potent inhibition of mTOR activation and associated vascular smooth muscle cell proliferation and survival.

Rapamycin inhibits mTOR and associated induced smooth muscle cell proliferation



Krymskaya, V., FASEB J 2011; 25:1922.

Systemic exposure to rapamycin, however, is burdened with numerous safety risks, including increased susceptibility to infection, lymphoma and malignancy: 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 (PML), Latent viral infection reactivation, Basal cell carcinoma, Squamous cell carcinoma, Melanoma, Lymphoma; 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 (ILD); Non-infectious pneumonitis; Bronchial anastomotic dehiscence; Increased creatinine; Decline in renal function; Proteinuria; Hypercholesterolemia: Hypertriglyceridemia, Hyperlipidemia; Diabetes mellitus; Hypokalemia; Anemia; Leukopenia; Neutropenia; Thrombocytopenia; Pancytopenia; Arthralgia; Myalgia; Bone necrosis; Hepatotoxicity (including fatal hepatic necrosis); Hepatic artery thrombosis; Lymphocele; Lymphedema; Ovarian cysts; Menstrual disorders (including amenorrhea, menorrhagia); Increased lactate dehydrogenase (LDH); Headache; Dizziness; Fever; Pain; Abdominal pain; Constipation; Diarrhea; Nausea; Stomatitis; Acne; Rash; Exfoliative dermatitis; Abnormal/impaired wound healing. Clinical use of oral rapamycin has been further complicated by poor aqueous solubility, first-pass metabolism in the liver, and low bioavailability. As such, the concentration of drug in the blood stream can vary significantly, with some patients observed having as much as eight times higher exposure than others administered the same dose. This variability necessitates continuous plasma monitoring and frequent dose adjustments. These issues with oral rapamycin have also precluded its use to treat disorders, such as pulmonary diseases, where the drug may otherwise find therapeutic utility.

LAM-001: Our Development Candidate for Serious, Underserved Pulmonary Diseases

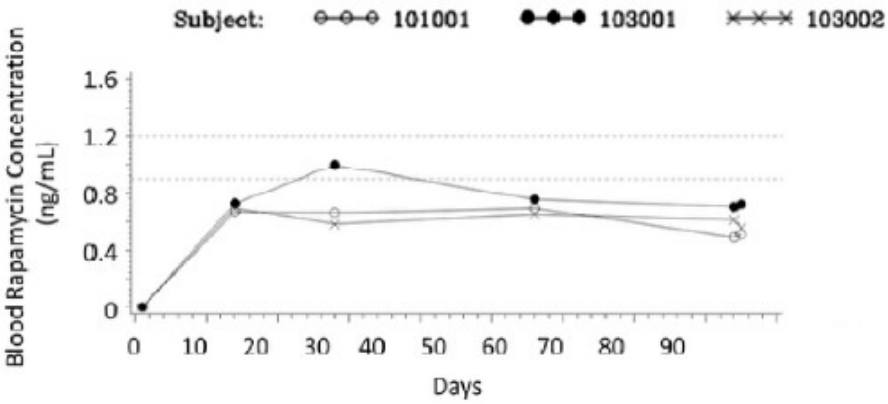
Our primary development candidate, LAM-001, is a proprietary inhaled dry powder formulation of rapamycin that is designed to provide numerous clinical advantages for the treatment of pulmonary diseases as compared to the oral formulation of rapamycin. These advantages include the targeted delivery of LAM-001 directly to the lung which is designed to enable higher local drug exposure and minimal systemic exposure, potentially resulting in an enhanced tolerability profile, as well as an easy-to-use, once-a-day dosing intended to increase convenience and improve patient compliance. We are currently developing LAM-001 as a potential disease modifying treatment for patients with three serious, underserved pulmonary diseases: PH-ILD, BOS and SAPH. We have completed a 10-patient Phase 2a trial of LAM-001 in PH and a 75-patient Phase 2b trial in PH-ILD is ongoing, with data expected in the first quarter of 2028. LAM-001 is also being evaluated in an ongoing Phase 2 clinical trial in BOS, which is fully enrolled with preliminary data projected to become available in the first quarter of 2027. We expect to initiate a Phase 2 trial to evaluate the use of LAM-001 as a treatment for SAPH in late 2026, with data expected in the fourth quarter of 2028. LAM-001 has been granted Orphan Drug Designation in the United States for BOS, sarcoidosis, pulmonary arterial hypertension and lymphangioleiomyomatosis. LAM-001 has been granted Orphan Drug Designation in the European Union for BOS and lymphangioleiomyomatosis. Orphan Drug Designation may provide certain development incentives and, if LAM-001 receives marketing approval for a designated indication, may make it eligible for orphan drug exclusivity for that approved indication, subject to applicable regulatory requirements.

Enhanced side-effect profile related to minimal systemic drug exposure

We evaluated LAM-001 in a Phase 1 clinical trial in adult female patients with LAM. The primary objective of the study was to evaluate the safety and tolerability of LAM-001 repeat dosing of 100 ug once daily over an initial 14-day period followed by an optional 84-day period. The secondary objective was pharmacokinetic assessments performed over an initial 14-day period followed by an optional 84-day period. Seven LAM patients received LAM-

001 during the initial 14-day period with three patients continuing dosing through the optional 84-day second period. In the trial, LAM-001 was well tolerated through the 12 weeks of daily dosing. All AEs, the most common of which was cough, were primarily mild with no trial withdrawals, dose adjustments or Grade 3 or 4 AEs. There were no drug related SAEs. The blood rapamycin concentration among the three optional 84-day trial extension participants was observed to remain relatively consistent at approximately <1 ng/ml. According to the oral rapamycin prescribing information, the target blood concentration of oral rapamycin for lymphangioleiomyomatosis patients ranges between 5 ng/ml to 15 ng/ml and target blood concentrations as high as 16—24 ng/ml are indicated for indications such as renal transplant.

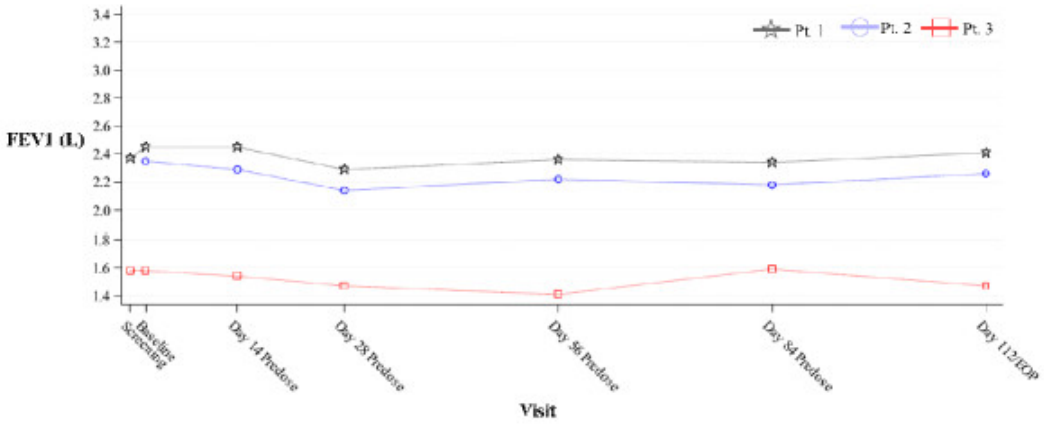
*A steady state blood concentration of 1 ng/ml was achieved at the 100 µg**



* LAM-001 Phase 1 repeat dose clinical study in patients with lymphangioleiomyomatosis

Importantly, stable maximal forced expiratory volume in one second ("FEV1") was observed across trial participants in both periods. The FEV1 values achieved by the three trial LAM patients who participated in the optional 84-day second period are provided below.

LAM patients achieved stable FEV1 values through the trial period.*



* LAM-001 Phase 1 repeat dose clinical study in patients with lymphangioleiomyomatosis

Easy-to-use once-daily dosing designed for increased patient convenience and compliance

To enhance dosing convenience, which is intended to bolster patient compliance, LAM-001 consists of a dry powder formulation of 1% rapamycin, contained in a dry powder capsule for once daily administration with a capsule based dry powder inhaler. Aerosol performance and nonclinical *in vivo* data support whole lung deposition achieved with the LAM-001 drug device combination. Capsule based Dry Powder inhalers are widely used for drugs delivered by DPI with millions of these devices sold annually. They are currently used to deliver numerous approved inhaled therapeutics including formoterol, budesonide, fluticasone and mannitol.

Targeted Disease Indications

We are currently developing LAM-001 as a potential disease modifying treatment for three serious, underserved pulmonary diseases: PH-ILD, BOS and SAPH. Rapamycin, the active ingredient in LAM-001, has demonstrated reduced pulmonary arterial smooth muscle cell hyperproliferation, improved endothelial cell function and decreased vascular remodeling in animal models of pulmonary hypertension. Separately, in BOS animal models, rapamycin has shown antifibrotic and immunoinflammatory-modulating activity, consistent with mTOR-dependent hyperactivation in this disease state. Combined, we believe these effects highlight the disease-modifying potential of LAM-001 across proliferative and fibrotic lung disease biology. A description of these diseases and considerations regarding the potential use of rapamycin to treat these diseases is discussed below.

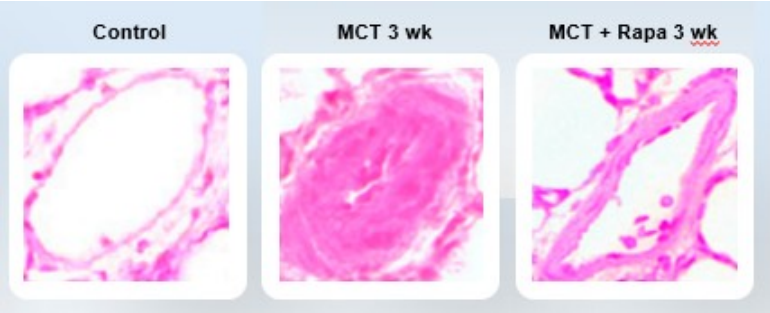
Pulmonary Hypertension associated with Interstitial Lung Disease (PH-ILD)

Pulmonary hypertension ("PH") is a heterogeneous collection of disorders characterized by elevated pressure in the pulmonary vasculature caused by adverse vascular remodeling with obstruction, stiffening and vasoconstriction leading to hypertrophy and failure of the heart's right ventricle. Patients diagnosed with PH are clinically segregated into one of five classifications related to differences in disease etiology, clinical presentation and hemodynamic characteristics. Group 3 patients have PH caused by a chronic lung disease and/or hypoxia, with chronic obstructive pulmonary disease ("COPD") and interstitial lung disease ("ILD") being two large, distinct subgroups within Group 3 PH. COPD includes patients with emphysema, characterized by the destruction of the alveoli, and chronic bronchitis, which involves inflammation and excessive mucus production. ILD includes a broad group of disorders, such as idiopathic pulmonary fibrosis or connective tissue disease-associated ILD, characterized by inflammation and fibrosis of the lung parenchyma ultimately leading to progressive scarring and impaired gas exchange. The coexistence of PH and ILD is associated with early morbidity and mortality. PH-ILD has a five-year survival rate of 23%, which is worse than patients with either PH (five-year survival rate of 54%) or ILD (five-year survival rate of 54%) alone. Patients with PH and idiopathic pulmonary fibrosis, a particularly aggressive form of PH-ILD, have an estimated mean survival of approximately 2 years. The addressable PH-ILD patient population in the US and Europe is approximately 200,000 combined.

Other than lung transplantation, there is no known cure for PH-ILD. Orally inhaled treprostinil, a prostacyclin mimetic which increases pulmonary vasodilation, is the only therapeutic currently approved by the FDA to treat PH-ILD. Both Tyvaso® and Yutrepia® are approved for increased exercise ability only. Tyvaso® is approved for delivery as either a nebulized liquid or dry powder formulation. Yutrepia® is approved for DPI only. Both Tyvaso® and Yutrepia® require the administration of between three to five doses daily.

Rodent models of PH provided insight into the role of mTOR in PH and the utility of rapamycin in modulating mTOR activity. Cultured pulmonary arterial smooth muscle cells ("PASMCs") taken from rats with monocrotaline ("MCT") induced PH, when exposed to various growth factors, exhibit an abnormal proliferative phenotype associated with the sustained activation of the mTOR signaling pathway. This phenotype was suppressed by rapamycin when added to PASMC cultures and when administered to rats, further supporting the involvement of mTOR signaling. Representative examples of the results observed in the *in vivo* studies are presented in the-cross sectional images below.

Rapamycin inhibited mTOR and reversed pulmonary artery smooth muscle cell (PASMC) proliferation in an in vivo study.



Houssaini, Am J Resp Cell Mol Bio 2013

Treatment with rapamycin, when administered at the same time as MCT induction, also resulted in a significantly lower rise in pulmonary arterial pressure and significantly lower vascular occlusion in comparison to untreated controls. Moreover, rapamycin was also observed to reduce right-ventricular atrophy.

Further evidence of the potential therapeutic benefit of rapamycin in treating PH was provided by a 10-patient, six month proof-of-concept ("POC") clinical trial conducted by Dr. Seyarth at the University of Leipzig, which evaluated the use of oral everolimus, a synthetic rapamycin, to treat both PAH patients and PH patients with chronic thromboembolic blockage, a Group 4 PH, who had been prescribed two or more vasodilators. Two patients dropped out of the trial, one following hospitalization due to clinical signs of heart failure (considered unlikely to be drug-related) and one following severe cough determined to be an episode of acute bronchitis (considered possibly drug related). Of the eight patients completing the trial, seven of the participants had significant improvement in PVR with PVR decreases of between 15% and 54% and one did not exhibit a change in PVR. The median PVR decrease for all 8 patients who completed the trial was 31%. Six of these eight trial participants improved 6MWD ranging from 28 to 240 meters while two patients decreased by 8 and 52 meters. The median 6MWD increase for all 8 patients who completed the trial was 62 meters. Reported side effects included elevation of cholesterol and triglyceride levels, none of which were reported as unexpected for patients receiving oral everolimus.

The results achieved in several *in vivo* nonclinical studies (e.g., hypoxia-, monocrotaline-, and Sugen/hypoxia- induced models of PH) with rapamycin and the 10-patient POC clinical trial encouraged us to pursue a clinical trial evaluating the clinical benefit of inhaled rapamycin to treat advanced PH. Accordingly, we initiated a multicenter, single-arm, open-label exploratory Phase 2a trial of LAM-001 as an add-on therapy in ten adult patients diagnosed with either PAH (Group 1 PH), PH-ILD (Group 3 PH) or SAPH (Group 5 PH) who remained symptomatic despite the use of standard of care therapies. Prior to receiving LAM-001, trial participants underwent pulmonary and radial artery catheterization to enable invasive cardiopulmonary exercise testing ("iCPET"), a diagnostic procedure that allows direct measurement of cardiac and pulmonary function in conjunction with a bicycle exercise test. Patients in the trial were then administered 100 µg of LAM-001 through DPI, once daily for 24 weeks, while remaining on a stable regimen of background therapy prior to enrollment and throughout the study. The majority of patients were on triple background therapy with all PH-ILD patients on inhaled, oral or subcutaneous treprostinil. Baseline iCPET measurements taken prior to administration of LAM-001 were compared to iCPET measurements taken immediately upon completion of the 24-week dosing period. The primary endpoints of the trial were peak oxygen uptake, or VO_2 Max, at 24 weeks as compared to baseline, in addition to safety and tolerability. Secondary endpoints included multiple hemodynamic measurements, including PVR, along with 6MWD and WHO functional class assessments.

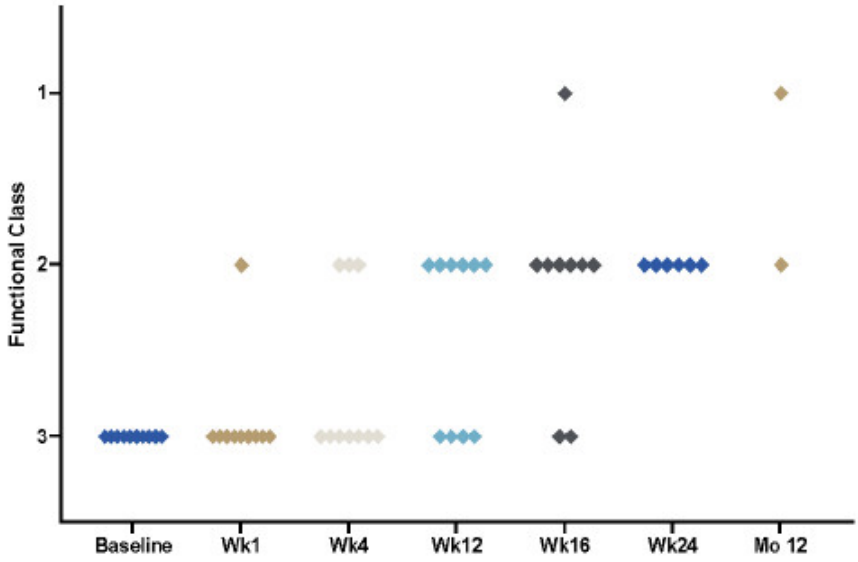
Five patients with PAH, four patients with PH-ILD and one patient with pulmonary sarcoidosis (Group 5 PH) were enrolled in the Phase 2a clinical trial. Six of the ten trial participants completed the full 24-week trial period, with the four discontinuations all deemed unrelated to the drug candidate. As noted in the table presented below, LAM-001 produced consistent, clinically relevant improvement across multiple endpoints, with mean PVR, 6MWD, VO_2 Max, NT-proBNP and FVC demonstrating notable improvements compared to baseline levels. Results of this Phase 2a trial were presented during the May 2026 American Thoracic Society meeting.

LAM-001 produced consistent, clinically relevant improvement across multiple Phase 2a endpoints.

	Evaluable Population	PH-ILD Population
	Mean	Mean
	N = 6	N = 4
Δ 6MWD (m)	+81.3	+67.4
Δ VO_2 Max (% Predicted)	+5.4%	+6.7%
% Δ PVR (exercise)	-25.5%	-35.3%
% Δ PVR (supine)	-28.1%	-33.9%
% Δ NT-proBNP	-29.0%	-28.8%
Δ FVC (% Pred)	+4.8%	+1.8%

Further evidence of the potential clinical benefit provided by LAM-001 was documented by the functional class improvement observed during the trial period. At baseline, all ten trial participants were assessed as WHO Functional Class III . A Functional Class III designation indicates that, while resting may be symptom free, activities such as normal chores around the house are greatly limited due to shortness of breath or exhaustion. By Week 12, the majority had improved to Functional Class II with all six participants who completed the trial achieving Functional Class II status at 24 weeks. Significantly, two patients who participated in the trial achieved Functional Class I status, defined as symptom free in both resting or physically active states, one during the trial period and another six-months into a trial extension period. Changes in functional class among Phase 2a trial participants is presented in the chart below.

Functional class improvement was observed among Phase 2a trial participants.



FC 1					1		1
FC 2		1	3	6	6	6	1
FC 3		9	7	4	2		
Total	10	10	10	10	9	6	2

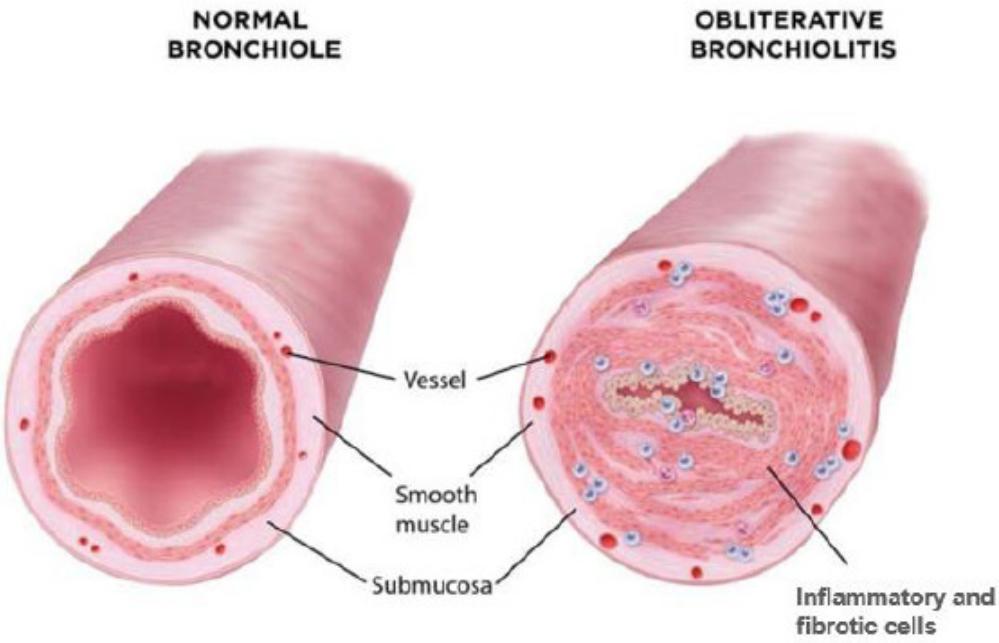
LAM-001 was well tolerated in this Phase 2a trial. No dose interruptions or adjustments were necessary due to AEs, and no participant discontinued the trial for reasons related to the drug candidate. Moreover, there were no drug-related SAEs, with the only reported drug-related AEs being one incidence of Grade 1 cough, one incidence of Grade 2 cough and one incidence of Grade 1 gingivitis.

In light of the favorable tolerability profile of LAM-001, together with the improvements observed in exercise capacity, hemodynamics, cardiac biomarkers and functional class, observed in these clinical trials, we initiated a Phase 2b evaluation of LAM-001 as a novel, disease modifying DPI therapy in adults between 18 and 70 years old (or above 70 years old with medical monitor approval) with Functional Class II or III PH-ILD whose PVR is 4 or greater and who are symptomatic despite stable background therapy. Approximately 75 participants, randomized into three 25-patient cohorts, are to be enrolled in this multi-center, placebo-controlled, double-blind trial. Two trial cohorts are to receive active drug candidate, one 100 µg once daily and the second 200 µg once daily, for 24 weeks. The third 25-person cohort is to receive placebo during the trial period. The primary endpoint of the Phase 2b trial is change in PVR. Secondary endpoints include change in 6MWD, time to and incidence of clinical worsening (defined as the occurrence of one of the following: death, lung transplantation or heart-lung transplantation, hospitalization related to worsening respiratory status/respiratory decompensation (>24 hrs), worsened WHO functional class, a decline in 6MWD from baseline of 15% or more, or >10% decline from baseline FVC). Safety and tolerability will also be assessed. Data from this ongoing Phase 2b clinical trial of LAM-001 is expected in the first quarter of 2028.

Bronchiolitis Obliterans post Lung Transplant

Obstructive chronic lung allograft dysfunction or BOS post lung transplant is a rare, progressive and irreversible lung disease characterized by the scarring and narrowing of the bronchioles, the smaller airways of the lung, leading to an irreversible decline in lung function and ultimate graft failure. As the disease progresses and lung function deteriorates, patients begin to experience shortness of breath, cough and wheezing. While the development of BOS post lung transplant varies in disease latency and severity, BOS is the leading cause of death following lung transplantation with a five-year survival rate of 54% among lung transplant recipients, which is well below that of other solid organ transplants, including heart (five-year survival of 72%), liver (five-year survival of 75%) and kidney (five-year survival of 74%). Disease progression is rapid with the median survival of lung transplant recipients post BOS onset of 2.5 years. Nearly all lung transplant patients will get BOS, with only 11% of lung transplant patients alive and free from BOS ten years after lung transplantation. While the definitive cause of BOS remains unknown, chronic alloimmune inflammation and dysregulated repair mechanisms drive progressive fibroproliferative remodeling of the small airways, resulting in sustained luminal narrowing and FEV1 decline. Other than a replacement transplant, there is no cure for BOS. In 2025, 3,490 lung transplants were performed in the US and we estimate approximately 4,000 will be conducted in 2026. The growth rate has accelerated in recent years over the 2,327 procedures in 2016. The increasing number of procedures is anticipated to lead to a growing prevalence of BOS. We estimate that the BOS patient population in the US and Europe combined will be approximately 30,000 by 2032.

BOS is characterized by the progressive occlusive narrowing of the bronchiole.



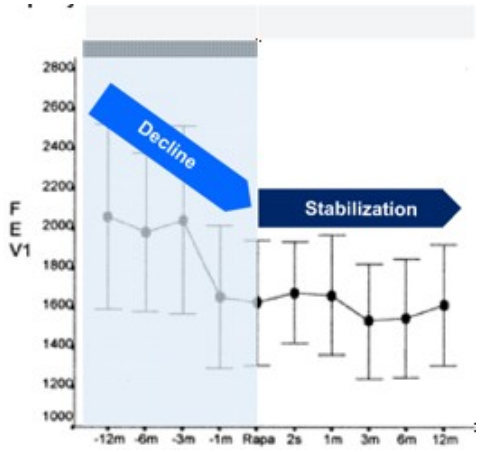
Standard treatment for BOS consists of long-term off-label immunosuppressive regimens that combine a calcineurin inhibitor, a cell cycle inhibitor and corticosteroids. Patients may also be administered fluticasone, oral montelukast and azithromycin (FAM) triple therapy. An alternate therapeutic combination replaces the cell cycle inhibitor with an oral mTOR inhibitor or adds an oral mTOR inhibitor to the regimen.

In the context of BOS, we believe mTOR inhibition with rapamycin may provide multifaceted benefit by suppressing not only adaptive immune responses but also fibroproliferative processes characteristic of obliterative bronchiolitis. Specifically, rapamycin inhibits effector T-cell differentiation and proliferation while promoting regulatory T cells (Tregs), reduces B-cell activation and antibody production (potentially mitigating antibody-mediated components of chronic rejection), and limits fibroblast proliferation, myofibroblast differentiation, and extracellular matrix deposition in the airways. It may also attenuate vascular smooth muscle cell hyperplasia, angiogenesis, and epithelial-mesenchymal transition that contribute to airway obliteration and remodeling. These effects collectively target the chronic alloimmune inflammation and dysregulated repair mechanisms driving progressive FEV1 decline in BOS.

One of the key metrics for BOS diagnosis, progression and prognosis is FEV1. BOS is defined as a sustained decline in FEV1 of 20% or more of post-transplant baseline levels provided that alternative causes of FEV1 decline have been excluded. BOS progression is tracked using a grading system ranging from Grade 0 (no BOS) to Grade 3 (Severe BOS), with each BOS grade defined by sequential declines in FEV1 as a percentage of post-transplant baseline FEV1 levels. Additionally, of note, each percentage decline in FEV1 has been found to be associated with a 3.4% increase in mortality.

The beneficial impact of oral rapamycin on progressive BOS has been demonstrated in small trials. In a third-party trial of eleven post lung transplant BOS patients whose mean FEV1 value declined over the 12 months prior to treatment with rapamycin, daily oral dosing of rapamycin was observed to stabilize or increase pulmonary function in 8 of the 11 participants. The oral rapamycin dose was adjusted weekly to achieve plasma rapamycin levels between 8 and 12 ng/ml. The benefit of rapamycin in these 11 participants is reflected in the graphic presented below.

Post lung transplant BOS patients benefitted from the use of oral rapamycin.



Hernandez, et. al. Transplantation Proceedings, 2005. DOI: 10.1016/j.transproceed.2005.09.191

As with PH-ILD, compliance with oral rapamycin dosing in this patient population has proven challenging due to side effects. Oral rapamycin is associated with numerous adverse events (“AEs”), including increased susceptibility to infection, lymphoma and malignancy: 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 (PML), 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 [BOOP], 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 (LDH); headache; dizziness; fever; pain; abdominal pain; constipation; diarrhea; nausea; stomatitis; acne; rash; exfoliative dermatitis; abnormal/impaired wound healing.

In a single-center study conducted by Dr. Stuckey at the University of Michigan in 49 patients administered oral rapamycin post lung transplant, 55% discontinued therapy due to adverse events including fatigue, edema, pneumonitis, and renal dysfunction. In addition, because of its low and variable oral bioavailability, rapamycin requires frequent plasma monitoring and dose adjustments to achieve target concentrations. We believe that the minimization of systemic toxicities through the use of an inhaled formulation of rapamycin may address tolerability issues while also enabling targeted drug delivery with higher local exposure. Additionally, we believe the once-daily, fixed dosed administration of LAM-001 has the potential to bolster convenience and ease-of-use for improved patient compliance.

To investigate the use of LAM-001 as DPI therapy to treat post lung transplant BOS, an investigator-initiated 48-week, double-blind, placebo-controlled, investigator-sponsored clinical trial involving 19 adult patients newly diagnosed with BOS who underwent a bilateral transplant is currently being conducted at UCSF. Patient enrollment is restricted to patients newly diagnosed with BOS (within the first 12 months of diagnosis) with FEV1 between 51% and 85% of best post-transplant FEV1. The 19 participants have been randomized into two cohorts, an active cohort receiving 100 µg LAM-001 once-daily and a placebo cohort for 48 weeks, followed by an open-label trial extension. The primary endpoint to be evaluated is percent change from baseline FEV1 at 48 weeks or termination of treatment (whichever occurs first). Secondary endpoints include the absolute change from baseline in FEV1 to 48 weeks or to termination of treatment (whichever occurs first), change in rate of progression in FEV1 in the time period (up to 12 months) prior to enrollment compared to rate of progression from enrollment to 48 weeks or to termination of treatment (whichever occurs first), and progression free survival (defined as time to earliest to occur of either a greater than 10% decline in FEV1 or death from respiratory failure or re-transplantation). Safety and tolerability will also be assessed. The trial was fully enrolled in January 2026, with top-line data expected in the first quarter of 2027.

Trial design provided for an interim assessment of patient status conducted in February 2026. At that time, 5 of the 19 trial participants enrolled in the ongoing blinded study were observed to have an FEV1 decline of 10% or more from the time of enrollment.

Sarcoidosis-Associated Pulmonary Hypertension (SAPH)

Sarcoidosis is a systemic inflammatory condition characterized by the formation of granulomas. An estimated 20% of patients with sarcoidosis develop a chronic and persistent condition which can result in irreversible fibrotic tissue damage and organ failure. While sarcoidosis can affect various organs and tissues, the lungs and pulmonary function are impacted in 90% of cases. The origin of sarcoidosis remains unknown.

SAPH, categorized within Group 5 PH, is an uncommon complication that affects an estimated 15% of patients with pulmonary sarcoidosis, and is associated with increased morbidity and mortality. With a five-year survival rate of 55%, SAPH has an 8 to 10 times higher mortality rate than pulmonary sarcoidosis alone. The incidence of SAPH in patients with pulmonary sarcoidosis is estimated to be between 6% and 28%, with the prevalence in pulmonary sarcoidosis patients awaiting lung transplant as high as 74%. There are collectively an estimated 60,000 patients with SAPH in the US and Europe.

There are no FDA-approved therapies for SAPH. Therapeutics used to treat PAH, including sildenafil, prostacyclins and endothelin receptor antagonists (ERA), are commonly used off label but with limited benefit. Approximately 22% of SAPH patients receive no PH specific therapy.

We believe scientific and clinical observations involving sarcoidosis provide compelling support for the potential therapeutic utility of DPI rapamycin to treat SAPH. mTOR activation is commonly seen in granulomas of patients across different tissues and has been shown to induce sarcoidosis-like granulomas in a mouse model. In addition, the one participant with pulmonary sarcoidosis included in our Phase 2a clinical trial demonstrated significant improvement after administration of LAM-001, including a 162 meter improvement in the 6MWD score at the Week 24 trial completion, a 41% and 66% improvement in the PVR resting and peak exercise tests, respectively, and a 7% improvement in VO_2 Max. As such, we expect to initiate a Phase 2 trial specifically to assess its use as a treatment for SAPH.

Other Development Candidates

We currently maintain ownership rights in additional drug candidates, AIT-101, AIT-102, and AIDE technology platform.

AIT-101

AIT-101 (apilimod dimesylate capsule) is an orally administered, potent and highly selective inhibitor of phosphatidylinositol-3-phosphate 5-kinase (PIKfyve) that has therapeutic potential in neurological diseases. Clinical studies of AIT-101 have been conducted in amyotrophic lateral sclerosis (“ALS”), non-hodgkin’s lymphoma (“NHL”), coronavirus disease 2019 (“COVID-19”), psoriasis, Crohn’s disease, and rheumatoid arthritis.

Apilimod binds to PIKfyve with high affinity (dissociation constant [KD] = 75 pM) and selectivity; in a panel of 456 normal and disease-related protein and lipid kinases, apilimod binding was only detected for PIKfyve. Three active metabolites of apilimod have been identified that also bind to PIKfyve with high affinity (KD range from 61 to 90 pM). The half maximal inhibitory concentration (IC50) is 14 nM and, in vitro, AIT-101 inhibition of PIKfyve has been shown to disrupt endosome and lysosome membrane trafficking.

In vitro and in vivo preclinical studies assessed the pharmacologic activity of AIT-101 in ALS models. AIT-101 significantly improved in a dose-dependent manner the survival of patient derived induced motor neurons (iMNs) with common ALS mutations (SOD1-G93A, TDP-43N930D or C9ORF72) following glutamate challenge. In a TDP-43 mouse model of ALS, AIT-101 treatment improved motor function, weight retention, and survival while reducing TDP-43 aggregates. Furthermore, AIT-101 cleared poly(GP) dipeptide repeat aggregates in brain tissues in a C9orf72 mouse model.

Most recently, a randomized, placebo controlled, Phase 2a study of AIT-101 in 15 ALS subjects with the c9orf72 mutation showed a favorable tolerability profile as well as a 72% decline in the polyGP biomarker. At this time, we anticipate that any further development of AIT-101 will be limited to non-dilutive funding sources obtained in partnership with government or academic collaborators.

AIT-102

AIT-102 is a novel molecule that was selected from a series of analogues of the natural product mithramycin. Mithramycin was originally isolated from the soil bacteria Streptomyces agrillaceus, and was first approved as a pharmaceutical agent in 1970. Manufacture of mithramycin for pharmaceutical use was discontinued in 2000. AIT-102 is an analogue of mithramycin that binds reversibly to DNA in the minor groove, notably in G/C-rich regions of DNA. Many of these G/C rich DNA sites function as promoter regions of growth-promoting genes and transcription factors.

AIT-102 was selected for its potential to have an improved therapeutic window over mithramycin, a distinction supported by mouse studies showing that mithramycin caused sharp AST/ALT elevations at its low MTD of 0.8 mg/kg, whereas AIT-102 produced no hepatic enzyme increases even at a ten-fold higher dose. AIT-102 has demonstrated high antitumor activity against numerous human, including pediatric, tumor cell lines, with 50% growth inhibition (GI_{50}) values between 10 nM and 1 μM. AIT-102 suppressed xenograft growth in a Ewing sarcoma model by attenuating EWS-FLI1 fusion activity as measured by NR0B1 GGAA-microsatelite response. In a SMARCB1-deficient rhabdoid tumor model, a single 3-day infusion produced tumor regressions and complete cures in a subset of xenograft-bearing mice; both increased H3K27 methylation, a marker of SWI/SNF displacement, and increased apoptosis were seen without significant DNA damage. Multiple mechanistic and in vivo studies have demonstrated that AIT-102 matched or exceeded the on-target activity of mithramycin while avoiding the toxicities that had limited mithramycin's clinical utility.

At this time, we anticipate that continued development of the AIT-102 program will be limited to non-dilutive support through the NCI-Next program, including CMC and GLP safety testing, and through partnership with academic collaborators.

AIDE Technology Platform

Prior to the 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.

Manufacturing and Supply

We do not own or operate manufacturing facilities, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We rely, and expect to continue to rely for the foreseeable future, on specialized external manufacturers to supply all our required raw materials, drug substance, drug product and the inhalation device needed to support our clinical development activities and, if approved, potential commercial demand. We have entered into a license and supply agreement with Plastiape S.p.A. that provides us with exclusive rights with respect to the capsule based dry powder inhaler, a capsule-based, refillable single-dose DPI, and rapamycin for LAM-001. We believe this outsourced manufacturing strategy allows us to maintain a capital-efficient operating model while focusing our internal resources on the development and future commercialization of LAM-001.

Competition

In recent years, the biotechnology and pharmaceutical industries have made substantial investments into the development of novel treatments for serious, underserved pulmonary diseases, such as PH-ILD, BOS and SAPH.

We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of pulmonary diseases and disorders.

In addition to Tyvaso®, sold by United Therapeutics Inc, and Yutrepia®, sold by Liquidia, the two currently FDA-approved inhaled treprostinil products used to treat patients with PH-ILD, commercial and academic preclinical studies and clinical trials are being undertaken by various parties to assess novel technologies and product candidates. Companies that compete with us directly on the level of the development of product candidates targeting PH-ILD include AllRock Bio, Apollo Therapeutics, Foresee Pharmaceuticals, Gossamer Bio, Halo Biosciences, Insmed Incorporated, Liquidia Corporation, Pharmosa Biopharm, Pulmovant, Tectonic Therapeutic, and United Therapeutics Corporation.

Companies that compete with us directly for BOS include Renovion, Sanofi, and Zambon.

There are no FDA-approved drugs specifically indicated for the treatment of SAPH. However, drugs indicated for PAH are frequently used off-label for the treatment of patients with SAPH, including drugs manufactured by Bayer, Eli Lilly, Gilead, Johnson & Johnson, Liquidia, Pfizer, and United Therapeutics.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in 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 one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offers. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have obtained patents and filed patent applications in the United States and other countries relating to certain of our proprietary technology, inventions, improvements, and product candidates, and are pursuing additional patent protection for them.

We seek to protect the proprietary technologies that we believe are important to our business by pursuing and maintaining patent protection in the United States and internationally. Our patent strategy is directed toward obtaining and maintaining claims covering compositions of matter, methods of use, formulations, and manufacturing processes related to LAM-001, as well as other inventions important to our business. We currently own issued U.S. and international patents directed to LAM-001 and related technologies. Our issued patents are expected to expire in 2035, without taking into account any potential patent term adjustments or extensions.

In addition to patent protection, we rely on trade secrets and proprietary know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. These include certain proprietary aspects of our manufacturing processes for LAM-001 and our other development candidates. We seek to protect our trade secrets through confidentiality and invention assignment agreements with our employees, consultants, contractors, and collaborators.

We also intend to rely on regulatory exclusivity where available, including orphan drug exclusivity, data exclusivity, and pediatric exclusivity, as well as patent term extensions under the Hatch-Waxman Act or equivalent foreign mechanisms, to supplement our patent protection and extend the commercial life of our product candidates.

As of June 22, 2026, we own 106 issued patents in 35 jurisdictions, including 16 issued U.S. patents and 88 issued foreign patents. We also own 9 pending U.S. non-provisional patent applications as well as approximately 25 corresponding patent applications pending in other jurisdictions and 1 pending U.S. provisional patent application . In addition, we own 2 pending international patent applications filed under the Patent Cooperation Treaty, which we plan to file nationally in the United States and other jurisdictions. Grouped into approximately 20 live patent families, these patents and applications provide robust patent protection for our product pipelines.

With regard to LAM-001, we own 9 issued U.S. patents with composition and method of use claims covering uses relating to this product. These issued US patents are expected to expire in 2034-2035. In addition, we own 25 related patents in Europe, Australia, North America, South America, and Asia that will expire between 2034-2035. We also own 5 pending U.S. non-provisional applications and 1 pending non-provisional application and 2 pending applications in China and WIPO. In addition, we own 2 pending Patent Cooperation Treaty (PCT) patent applications and provisional applications directed to composition of matter and new uses relating to this product. If granted, these pending applications would expire in 2035 – 2047.

With regard to AIT-101, we own 7 issued U.S. patents. These U.S. patents are expected to expire in 2034-2044. In addition, we own 4 related patents in Australia, Canada and Japan that are expected to expire in 2037-2039. We also own 4 pending U.S. applications and 24 related pending applications in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, South Korea & Taiwan. If granted these pending applications would expire in 2039-2044.

With regard to AIT-102, we own 2 issued U.S. Patents. These U.S. patents are expected to expire in 2030-2037. In addition we own 16 related patents in Europe (France, Germany, Italy, Liechtenstein, Spain, Switzerland, and the United Kingdom) that are expected to expire in 2030-2036.

With regard to Quince legacy assets, we own 22 issued patents, including 3 issued U.S. patents, and 5 pending applications, including 1 pending U.S. application and 4 pending applications outside the United States. The issued patent rights are expected to expire between 2027-2042 and, if granted, the pending applications would expire in 2043.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of LAM-001, future product candidates, and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges, preserving the confidentiality of our trade secrets, and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier

filed patent. In certain foreign jurisdictions, similar extensions as compensation for regulatory delays are also available. The actual protection afforded by a patent varies on a claim by claim and country by country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. In particular, up to a five-year extension may be available in Europe and Japan. We plan to seek such extensions as appropriate.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, aspects of our manufacturing processes for LAM-001. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restrictions on access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, such individuals may breach such agreements and disclose our proprietary information including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Government Regulation

In the United States, pharmaceutical products are approved by the FDA for marketing under the Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDCA and its implementing regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, recordkeeping, distribution, marketing, sales, import, export, reporting, advertising, and other promotional practices involving pharmaceutical products. FDA clearance of an IND application must be obtained before commencing clinical testing of pharmaceutical products. FDA approval of an NDA must be obtained before marketing of pharmaceutical products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Development Process

The process required by the FDA before a pharmaceutical product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- preparation of clinical trial material in accordance with cGMPs;
- submission to the FDA of an application for an IND application, which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB"), reviewing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity, potency, and efficacy, of the proposed pharmaceutical product for its intended use;
- submission to the FDA of an NDA for marketing approval that includes substantive evidence of safety and efficacy from results of nonclinical testing and clinical trials as well as payment of a substantial user fee;
- satisfactory completion of an FDA inspection prior to NDA approval of the manufacturing facility or facilities where the drug substance or finished pharmaceutical product is produced to assess compliance with cGMPs, to assure that the facilities, methods, and controls are adequate to preserve the final finished product's identity, strength, quality, and purity;

- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the NDA;
- potential FDA advisory committee meeting to elicit expert input on critical issues and including a vote by external committee members;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post approval studies.

Before testing any pharmaceutical product candidate in humans, the product candidate enters the preclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, pharmacology, toxicity, and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA as part of the IND. Some nonclinical testing typically continues after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA requests certain changes to a protocol before the trial can begin, or the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not be recommenced without FDA authorization and then only under terms authorized by the FDA.

Clinical trials may involve the administration of the pharmaceutical product candidate to healthy volunteers or subjects under the supervision of qualified investigators. Clinical trials involving some products for certain diseases, including some rare diseases may begin with testing in patients with the disease. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that ensure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects or their legal representatives provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1***. The pharmaceutical product is initially introduced into healthy human subjects and tested for safety. In the case of some products for rare diseases, the initial human testing is often conducted in patients.

- ***Phase 2***. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance, optimal dosage, and dosing schedule.
- ***Phase 3***. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. In rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated by the Phase 2 trial.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up or for additional efficacy confirmation

During all phases of clinical development, the FDA requires extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of serious suspected adverse reactions over those listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for such reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the study drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the pharmaceutical product as well as finalize a well controlled process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals. Information about certain clinical trials must be submitted within specific timeframes for public dissemination on the clinicaltrials.gov website.

U.S. Review and Approval Processes

After the completion of clinical trials of a pharmaceutical product , FDA approval of an NDA must be obtained before commercial marketing of the product begins. The NDA must include results of product development, laboratory, and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling, and other relevant information. Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each NDA may be accompanied by a significant user fee. The sponsor of an approved application is also subject to an annual program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews an NDA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The application also needs to be published and submitted in an electronic format that can be processed through the FDA's electronic systems. If the electronic submission is not compatible with the FDA's systems, the NDA can be refused for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to ensure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a REMS is necessary to ensure the safe use of the pharmaceutical product . If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS (Risk Evaluation and Mitigation Strategy); the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to ensure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria for approval and issue a complete response letter that describes all the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, such as requiring labeling changes, or major, such as requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a pharmaceutical product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment.

One of the performance goals agreed to by the FDA under the PDUFA is to review standard NDAs in ten months from filing and priority NDAs in six months from filing, in each case from the acceptance for filing date that is 60 days after the applicant submits the NDA. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

505(b)(2) Approval Process

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act provides a regulatory pathway for certain new drug applications, or NDAs, that permits an applicant to rely, in part, without a right of reference, to the FDA's previous findings of safety and effectiveness for an approved drug or published scientific literature. 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. The type and amount of additional information required by the FDA depend on the nature of the proposed product and the differences between that product and the reference product or underlying literature. As a result, a 505(b)(2) application may require one or more clinical, nonclinical, pharmacokinetic, bioavailability, bioequivalence or other studies, as well as a full chemistry, manufacturing and controls package.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Following approval, the manufacturing facilities are subject to inspections by the FDA, and such inspections may result in an issuance of FDA Form 483 deficiency observations, untitled letter, or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of any manufacturing changes, a determination needs to be made regarding whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further action. Product reports are required to be submitted annually. Other post-approval requirements applicable to pharmaceutical products include reporting of cGMP deviations that may affect the identity, potency, purity, and overall safety of a distributed product, recordkeeping requirements, reporting of adverse events, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies, and they are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain cGMP compliance. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are

otherwise unfit for distribution in the United States. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA , including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation ("ODD"), to a pharmaceutical product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a pharmaceutical product available in the United States for this type of disease or condition will be recovered from sales of the product. ODD must be requested before submitting an NDA. After the FDA grants ODD, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has ODD receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same pharmaceutical product for the same indication for seven years, except in limited circumstances, such as not being able to supply the product for patients or showing clinical superiority to the product with orphan exclusivity.

Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same pharmaceutical product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a pharmaceutical product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, priority review, accelerated approval, and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of pharmaceutical products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new pharmaceutical products to patients earlier than under standard FDA review procedures. To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a pharmaceutical product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track NDA before the application is complete, a process known as rolling review.

The FDA may grant priority review designation to pharmaceutical products that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Most products that are eligible for Fast Track designation may also be considered appropriate to receive a priority review. In addition, pharmaceutical products that are studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments

may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the pharmaceutical product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a pharmaceutical product receiving accelerated approval to perform adequate and well-controlled post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or another clinical endpoint. The FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. The FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period.

Moreover, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a pharmaceutical product that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the pharmaceutical product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Furthermore, fast-track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval and may not ultimately expedite the development or approval process.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical studies, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In the European Union, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. In the European Union, clinical trials of investigational medicinal products are governed by Regulation (EU) No. 536/2014, commonly referred to as the Clinical Trials Regulation, or CTR. Under the CTR, a sponsor seeking to conduct a clinical trial in one or more EU Member States submits a clinical trial application through the Clinical Trials Information System, or CTIS. The application dossier is generally divided into Part I and Part II. Part I includes the scientific and medicinal product documentation and is subject to a coordinated assessment led by a reporting Member State, with input from the other concerned Member States in which the sponsor seeks authorization. Part II includes Member State-specific and patient-facing documentation, such as informed consent materials and certain local regulatory documents, and is assessed separately by each concerned Member State in accordance with its national requirements. Ethics committees continue to play a role in the review process as determined by the national law of each concerned Member State, while the overall procedures, decision-making framework and applicable timelines are established by the CTR. The CTR also provides a harmonized framework for ongoing clinical trial supervision and for the submission of substantial modifications, safety reports and other lifecycle-related communications through CTIS.

In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence marketing of the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

To obtain regulatory approval of our medicinal products under the European Union regulatory system, we are required to submit a marketing authorization application ("MAA"), to be assessed in the centralized procedure. The centralized procedure allows applicants to obtain a marketing authorization ("MA") that is valid throughout the European Union, and the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway) ("EEA"). It is compulsory for medicinal products manufactured using biotechnological processes, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and human products containing a new active substance which is not authorized in the European Union and which is intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other immune dysfunctions, viral diseases or diabetes. The centralized procedure is optional for any other products containing new active substances not authorized in the European Union or for products which constitute a significant therapeutic, scientific, or technical innovation or for which a centralized authorization is in the interests of patients at European Union level. When a company wishes to place on the market a medicinal product that is eligible for the centralized procedure, it sends an application directly to the EMA, to be assessed by the Committee for Medicinal Products for Human Use ("CHMP"). The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety, and efficacy requirements, and whether the product has a positive risk/benefit profile. The procedure results in a European Commission decision, which is valid in all European Union Member States. The centralized procedure is as follows: full copies of the MAA are sent to a rapporteur and a co-rapporteur designated by the competent EMA scientific committee. They coordinate the EMA's scientific assessment of the medicinal product and prepare draft reports. Once the draft reports are prepared (other experts might be called upon for this purpose), they are sent to the CHMP, whose comments or objections are communicated to the applicant. The rapporteur is therefore the privileged interlocutor of the applicant and continues to play this role even after the MA has been granted.

The rapporteur and co-rapporteur then assess the applicant's replies, submit them for discussion to the CHMP, and taking into account the conclusions of this debate, prepare a final assessment report. Once the evaluation is completed, the CHMP gives a favorable or unfavorable opinion as to whether to grant the authorization. When the opinion is favorable, it shall include the draft summary of product characteristics ("SmPC"), the package leaflet, and the texts proposed for the various packaging materials. The time limit for the evaluation procedure is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). The EMA then has fifteen days to forward its opinion to the European Commission, which will make a binding decision on the grant of an MA within 67 days of the receipt of the CHMP opinion.

There are two other procedures in the European Union for the grant of an MA in multiple European Union Member States. The decentralized procedure provides for approval by one or more other, or Concerned, Member States, of an assessment of an application performed by one Member State, known as the Reference Member State. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft SmPC, and draft labeling and package leaflet, to the Reference Member State and Concerned Member States. The Reference Member State prepares a draft assessment and draft of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the Reference Member State's assessment report, each Concerned Member State must decide whether to approve the assessment report and related materials. If a Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all Member States. Where a product has already been authorized for marketing in a European Union Member State, this national MA can be recognized in other Member States through the mutual recognition procedure.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it is intended for the diagnosis, prevention, or treatment of a life-threatening or

chronically debilitating condition that affects no more than five in 10,000 persons in the European Union when the application is made. In addition, orphan designation can be granted if the product is intended for a life threatening, seriously debilitating, or serious and chronic condition in the European Union where, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in its development. Orphan designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing, or treating the applicable orphan condition or, if such a method exists, the proposed orphan medicinal product would be of significant benefit to patients affected by such condition, as defined in Regulation (EC) 847/2000.

Orphan designation provides opportunities for fee reductions, protocol assistance, and access to the centralized procedure. Fee reductions are limited to the first year after an MA, except for small and medium enterprises. In addition, if a product which has an orphan designation subsequently receives a centralized MA for the indication for which it has such designation, the product is entitled to orphan market exclusivity, which means the EMA may not approve any other application to market a similar medicinal product for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The exclusivity period may be reduced to six years if, at the end of the fifth year, it is shown that the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, an MA may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior;
- the MA holder of the authorized product consents to a second orphan medicinal product application; or
- the MA holder of the authorized product cannot supply enough orphan medicinal product.

A pediatric investigation plan ("PIP") in the European Union is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for MAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when an MA holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized across the European Union with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate ("SPC") by six months (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires). This is the case even when the studies' results are negative. For orphan medicinal products, the incentive is an additional two years of market exclusivity. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use MA ("PUMA"). If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

In March 2016, the EMA launched an initiative, the PRIority Medicines ("PRIME") scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a

candidate medicine has been selected for the PRIME scheme, a dedicated contact and rapporteur from the CHMP or from the Committee for Advanced Therapies ("CAT") are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

The aforementioned European Union rules are generally applicable in the EEA. The United Kingdom left the European Union on January 31, 2020, and the United Kingdom and the European Union have concluded a trade and cooperation agreement ("TCA") which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). Except with respect to the new European Union Clinical Trials Regulation, the regulatory regime in Great Britain largely aligns with current European Union medicines regulations. However, it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of European Union pharmaceutical legislation under the TCA, under a new framework mentioned below which will be put in place by the Medicines and Healthcare products Regulatory Agency ("MHRA"), the United Kingdom's medicines regulator (MHRA) has stated that, beginning in January 1, 2024, it will take into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a Great Britain MA.

On February 27, 2023, the United Kingdom government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA will be responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single United Kingdom-wide MA will be granted by the MHRA for all medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. The Windsor Framework was approved by the European Union-United Kingdom Joint Committee on March 24, 2023, so the United Kingdom government and the European Union will enact legislative measures to bring it into law.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. All existing European Union MAs for centrally authorized products were automatically converted (grandfathered) into United Kingdom MAs free of charge on January 1, 2021. For a period of three years from January 1, 2021, the MHRA could rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. On January 24, 2023, the MHRA announced that a new international recognition framework would be put in place beginning January 1, 2024, which would have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new Great Britain MA.

There is now no pre-MA orphan designation in Great Britain. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the Great Britain market, i.e., the prevalence of the condition in Great Britain (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in Great Britain or the European Union, wherever is earliest.

Healthcare Laws and Regulations

Health care providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state health care laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, 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, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, directly or indirectly, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits 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 health care benefits, items or services;
- the Foreign Corrupt Practices ACT ("FCPA") which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to health care items or services that are reimbursed by non-government third-party payors, including private insurers.

Additionally, some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. Further, 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 manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of such laws may result in significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, diminished profits and future earnings, and the curtailment or restructuring of operations.

Pharmaceutical Coverage, Pricing and Reimbursement

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Even if we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drug. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Further, the U.S. Department of Health and Human Services ("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 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.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other foreign jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amounts that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Healthcare Reform

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful

Bill Act (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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Other legislative changes have been proposed and adopted in the United States 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 HHS, the FDA, the U.S. Centers for Medicare and Medicaid Services ("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 several 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 certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again ("MAHA") 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 ("PBM") 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, if approved.

Data Privacy

In the ordinary course of our business, we process personal or sensitive data, including data related to participants in clinical trials. Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. We are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Numerous U.S. states have enacted comprehensive consumer 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. Generally, the U.S. state comprehensive consumer privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, as the exercise of these rights may impact our business. 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 and private actions in certain circumstances. Outside the United States, there exist data protection laws such as the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), under which companies, have compliance obligations and in the event of non-compliance with relevant obligations, may face, among other consequences, temporary or definitive bans on data processing and other corrective actions; monetary fines; and private litigation.

Employees and Human Capital Resources

As of May 31, 2026, we had 16 employees, all of whom were full-time and 6 of whom were engaged in research and development activities. 4 of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters are currently located in South San Francisco, California, where we signed a lease agreement for a smaller office space that expires in November 2026. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may be subject to legal proceedings or be subject to claims arising in the ordinary course of business. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Corporate Information

We were incorporated in Delaware on June 20, 2012. Effective August 1, 2022, the Company, previously named Cortexyme, Inc., changed its name to Quince Therapeutics, Inc. Our principal executive offices are located at 611 Gateway Blvd, Suite 273, South San Francisco, CA 94080, and our general telephone number is (415) 910-5717. Our website address is www.quincetx.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not incorporated herein.

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other information with the SEC. Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

RISK FACTORS

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. While we generated net income of $35.9 million for the three months ended March 31, 2026, our net loss was $15.0 million for the three months ended March 31, 2026 and 2025, respectively, and $84.0 million and $56.8 million for the years ended December 31, 2025 and 2024, respectively. As of March 31, 2026 and as of December 31, 2025, we had an accumulated deficit of $424.5 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 three months ended March 31, 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 more narrow 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 receive 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 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 three months ended March 31, 2026, we utilized our ATM program to raise net proceeds of approximately $15.0 million by issuing 400,925 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, 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.

Exhibit 99.6

Orphai Therapeutics, Inc.

Financial Statements as of and for the
Years Ended December 31, 2025 and 2024,
Independent Auditor’s Report

ORPHAI THERAPEUTICS, INC.

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INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of Quince Therapeutics, Inc.

Opinion

We have audited the financial statements of Orphai Therapeutics, Inc. (the "Company"), which comprise the balance sheets as of December 31, 2025 and 2024, and the related statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes to the financial statements (collectively referred to as the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audits in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring net losses and cash flows used in operations, and on May 18, 2026, the Company was acquired by Quince Therapeutics, Inc. (the "Acquirer") and the Acquirer of the Company may be required to make significant cash payments to holders of Series C Non-Voting Convertible Preferred Stock that could substantially reduce the Company's available cash and cash equivalents. As a result, the Company has stated that substantial doubt exists about its ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

Exercise professional judgment and maintain professional skepticism throughout the audit.

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

/s/ Deloitte & Touche LLP

July 29, 2026

ORPHAI THERAPEUTICS, INC.

BALANCE SHEETS
AS OF DECEMBER 31, 2025 AND 2024

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	658,248	2,220,979
Deposits	15,000	143,480
Research and development tax credit receivable	12,822	31,618
Prepaid expenses	330,430	269,896
Miscellaneous receivables	5,100	5,100
Total current assets	**1,021,600**	**2,671,073**
Property and equipment, net	—	1,270
Total assets	**1,021,600**	**2,672,343**
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	1,533,558	223,622
Accrued expenses	449,207	673,168
Convertible notes, current	8,492,726	—
Total current liabilities	**10,475,491**	**896,790**
Convertible notes, noncurrent	—	2,462,714
Warrants	3,183,628	863,694
Total liabilities	**13,659,119**	**4,223,198**
Commitments and contingencies		
Redeemable convertible preferred stock		
Redeemable convertible preferred stock, $0.0001 par value—13,583,324 shares authorized as of December 31, 2025 and 2024, respectively. 10,836,011 shares issued and outstanding as of December 31, 2025 and 2024, respectively and liquidation value of $105,133,172 as of December 31, 2025 and 2024, respectively	102,006,774	102,006,774
Stockholders' equity (deficit)		
Common stock, $0.0001 par value—22,500,000 shares authorized as of December 31, 2025 and 2024, respectively. 397,749 shares issued and outstanding as of December 31, 2025 and 2024, respectively	398	398
Additional paid-in capital	12,366,487	12,161,938
Accumulated deficit	(127,011,178)	(115,719,965)
Total stockholders' deficit	**(114,644,293)**	**(103,557,629)**
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	**1,021,600**	**2,672,343**

ORPHAI THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

	December 31, 2025	December 31, 2024
Operating expenses:		
Research and development	4,003,762	$ 4,872,915
General and administrative	2,161,623	5,345,002
Total operating expenses	**6,165,385**	**$ 10,217,917**
Loss from operations	**(6,165,385)**	**$(10,217,917)**
Nonoperating income:		
Interest income	32,192	137,683
Change in fair value of notes	(1,412,937)	(512,168)
Change in fair value of warrants	(2,239,300)	(64,241)
Loss on exchange of convertible notes	(1,501,535)	—
Other expense, net	(4,248)	(15,552)
Total nonoperating expense	**(5,125,828)**	**$ (454,278)**
Net loss and comprehensive loss	**(11,291,213)**	**$(10,672,195)**

ORPHAI THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

	Redeemable Convertible Preferred Stock		Stockholders' Deficit				
			Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
January 1, 2024	**10,836,011**	**$104,390,444**	**390,249**	**$ 390**	**$ 5,946,036**	**$ (107,431,440)**	**$ (101,485,014)**
Net loss	—	—	—	—	—	(10,672,195)	(10,672,195)
Series A extinguishment	—	(2,383,670)	—	—	—	2,383,670	2,383,670
Common stock issued upon exercise stock option	—	—	7,500	8	2,992	—	3,000
Stock-based compensation expense	—	—	—	—	6,212,910	—	6,212,910
December 31, 2024	**10,836,011**	**$102,006,774**	**397,749**	**$ 398**	**$ 12,161,938**	**$ (115,719,965)**	**$ (103,557,629)**
Net loss	—	—	—	—	—	(11,291,213)	(11,291,213)
Stock-based compensation expense	—	—	—	—	204,549	—	204,549
December 31, 2025	**10,836,011**	**$102,006,774**	**397,749**	**$ 398**	**$ 12,366,487**	**$ (127,011,178)**	**$ (114,644,293)**

ORPHAI THERAPEUTICS, INC.

STATEMENT OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

	December 31, 2025	December 31, 2024
Cash flows from operating activities:		
Net loss	$(11,291,213)	$(10,672,195)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,270	16,118
Change in fair value of notes and warrants	3,652,237	576,408
Exchange of senior convertible notes for new convertible notes	1,501,534	—
Loss on disposal of property and equipment	—	42,115
Stock-based compensation expense	204,549	6,212,910
Changes in operating assets and liabilities:		
Deposits	128,480	19,000
Prepaid expenses	(60,534)	(51,841)
R&D tax credit receivable	18,796	—
Accounts payable	1,309,936	(206,899)
Accrued expenses	(223,961)	(2,449,657)
Net cash used in operating activities	(4,758,906)	(6,514,041)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	3,000
Proceeds from issuance of convertible notes	3,196,175	2,750,000
Net cash provided by financing activities	3,196,175	2,753,000
Net decrease in cash and cash equivalents	(1,562,731)	(3,761,041)
Cash and cash equivalents, beginning of year	2,220,979	5,982,020
Cash and cash equivalents, end of year	$ 658,248	$ 2,220,979

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Orphai Therapeutics, Inc. (the "Company"), formerly known as AI Therapeutics, Inc., and LAM Therapeutics, Inc., was incorporated as a Delaware corporation on March 4, 2013. 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. The Company is currently developing LAM-001 for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD), bronchiolitis obliterans syndrome (BOS), and sarcoidosis associated pulmonary hypertension (SAPH).

Liquidity and Going Concern—The accompanying financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since its inception, the Company has generated no revenue and has funded its operations primarily through the issuance of preferred stock and convertible promissory notes to private investors. The Company has incurred recurring operating losses and negative cash flows from operations since inception, including a net loss of $11,291,213 for the year ended December 31, 2025, and had an accumulated deficit of $127,011,178 as of December 31, 2025. The Company expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future as it continues to advance its research and development activities.

The Company's existing cash and cash equivalents were not sufficient to fund its planned operations and satisfy its obligations as they became due for a period of at least twelve months from the date these financial statements are available to be issued. Accordingly, management determined that conditions existed that raised substantial doubt about the Company's ability to continue as a going concern.

In order to mitigate these conditions, on May 18, 2026, the Company was acquired by Quince Therapeutics, Inc. ("Quince"). Concurrent with the closing of the merger, Quince completed a private placement financing that generated gross proceeds of approximately $115,000,000 through the issuance of Quince Series C Convertible Preferred Stock and related warrants (see Note 11, Subsequent Events). In connection with the merger, holders of the Company's equity securities received Quince common stock and Quince Series C Convertible Preferred Stock, the Company's outstanding convertible notes converted into equity immediately prior to the effective time of the Merger in accordance with their terms, and the Company's outstanding options and warrants were assumed or exchanged for corresponding Quince equity instruments.

The Quince Series C Convertible Preferred Stock issued in the merger and the private placement financing are convertible into Quince common stock upon receipt of the requisite stockholder approval under applicable Nasdaq listing rules. Under the terms of the Certificate of Designation, if Quince fails to obtain the required stockholder approval or otherwise fails to timely deliver shares of common stock upon conversion following the applicable trigger date, which is the date on which the Series C Preferred

Stock becomes convertible following receipt of the required stockholder approval, holders of the Series C Convertible Preferred Stock are entitled to require Quince to make cash payments based on the 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 the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within the Company's control. Management's plan to convert the Series C Convertible Preferred Stock into common stock and therefore remove the requirement to make cash payment based on the value of the undelivered shares is the execution of a stockholder proxy vote set to take place in or around September 2026. 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 financial statements do not include any adjustments relating to the recoverability and classification of recorded assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation—The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

Reverse Stock Split—In February 2026, the Company effected a 1-for-10 reverse stock split of its common stock. Accordingly, all stockholders of record received one issued and outstanding common share in exchange for ten outstanding common shares. No fractional shares were issued in connection with the reverse split, and any fractional shares were rounded to the nearest whole share. All share and per-share amounts in these financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents. As of December 31, 2025 and 2024, substantially all the Company's cash and cash equivalents were invested in money market funds at one financial institution. The Company also maintains balances in various operating accounts above federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Use of Estimates—The preparation of the financial statements in conformity with US GAAP requires the Company to make estimates and assumptions about future events that affect the amounts reported in its financial statements and accompanying notes. Future events and their effects cannot be determined with certainty. On an ongoing basis, management evaluates these estimates and assumptions. Significant estimates and assumptions include assumptions underlying the fair value used in the calculation of the stock-based compensation, the fair value of warrants and fair values of convertible notes. In addition, management makes assumptions related to work completed but not yet billed by third party vendors to calculate prepaid expenses and accrued expenses.

Cash and Cash Equivalents—All highly liquid investments purchased with a maturity of three months or less are cash equivalents. As of December 31, 2025 and 2024, cash and cash equivalents consist of bank depository accounts and money market funds.

Research and Development Tax Credit Receivable—Research and development tax credit receivable includes monies to be received from the State of Connecticut for research and development tax credits. These research and development tax credits are exchanged for a cash refund and are typically collected within one year from the date the tax return is filed with the state. The credits are recognized as an offset to research and development expenses in the statements of operations and comprehensive loss in the annual period the corresponding expenses were incurred.

Research and Development—Research and development expenses are composed of costs incurred in performing research and development activities, including personnel salaries, benefits, and equity-based compensation; external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; the cost of developing and manufacturing clinical study materials, program regulatory costs, expenses associated with obligations under asset acquisitions, license agreements, and other direct and indirect costs. Costs incurred in connection with research and development activities are expensed as incurred. Costs are considered incurred based on an evaluation of the progress to completion of each contract using information and data provided by the respective vendors, including the Company's clinical sites. Depending upon the timing of invoicing by the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid expenses or accrued expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Convertible Notes and Warrant Liabilities—The Company has elected the fair value option under Accounting Standards Codification ("ASC 825"), Financial Instruments, for its convertible notes. The fair value option was elected because the convertible notes contain embedded features and contingent settlement provisions that could otherwise require bifurcation and separate accounting. The election results in a single measurement attribute for the entire convertible notes and eliminates the need to separately account for embedded features and contingent settlement provisions. Accordingly, transaction costs incurred upon issuance of the convertible notes are recognized as incurred in the statements of operations and comprehensive loss within other expense, net.

Convertible notes are initially measured at fair value upon issuance and subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in the statements of operations and comprehensive loss within non-operating expense. The Company has elected to report changes in fair value attributable to the accrual of contractual interest as part of the overall change in fair value recognized in earnings. Accordingly, contractual interest is not presented separately as interest expense.

The fair value of the convertible notes is estimated using scenario-based valuation techniques that considered the probabilities of financing, conversion, redemption and other settlement scenarios. Significant assumptions include the expected timing and probability of such scenarios, market participant discount rates, contractual terms and other relevant market participant assumptions. Changes in fair value, including those attributable to changes in instrument-specific credit risk, are recognized in the period incurred. Because the valuation incorporates significant unobservable inputs, the fair value measurement of the convertible notes is classified within Level 3 of the fair value hierarchy. The valuation of the convertible notes incorporates market participant assumptions regarding instrument-specific credit risk as one of several unobservable inputs used in estimating fair value. Changes in market participant credit risk remained relatively stable during the periods presented and changes in the fair value of the convertible notes were driven primarily by revisions to probability-

weighted financing and liquidity-event assumptions, contractual terms, and expected timing of future events rather than changes in instrument-specific credit risk. Accordingly, the Company concluded that changes attributable solely to instrument-specific credit risk were not material for the changes in fair value for the years ended December 31, 2024 and 2025, respectively. Additional information regarding the Company's fair value measurements, including significant assumptions used in the valuation of the convertible notes, is included in Note 3, Fair Value Measurements.

The Company accounts for certain freestanding warrants as liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity, because the warrants are exercisable into preferred stock that is redeemable upon the occurrence of events not solely within the Company's control. Warrant liabilities are initially measured at fair value upon issuance and subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in the statements of operations and comprehensive loss within non-operating expense.

The fair value of the warrant liabilities is determined using valuation methodologies that incorporate probability-weighted financing, conversion, redemption and other liquidity-event scenarios, together with assumptions regarding the expected timing and probability of each scenario, required market participant rates of return and other relevant inputs. Because the valuation incorporates significant unobservable inputs, the fair value measurement of the warrant liabilities is classified within Level 3 of the fair value hierarchy.

Additional information regarding the valuation methodologies, significant assumptions, fair value hierarchy classifications and changes in fair value is included in Note 3, Fair Value Measurements. For the convertible notes, Note 5 also includes the relationship between the aggregate fair value and the unpaid principal balance as required by ASC 825.

Redeemable Convertible Preferred Stock—The redeemable convertible preferred stock is recorded outside of permanent equity because, while it is not mandatorily redeemable, in certain events which are not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "Deemed Liquidation Event"), the redeemable convertible preferred stock may become redeemable. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to its liquidation value because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock is not probable of occurring as of December 31, 2025. Subsequent adjustments to the carrying values of convertible preferred stocks to the liquidation value will be made only when it becomes probable that such a deemed liquidation event will occur.

Stock-Based Compensation—The measurement of stock-based compensation expense is based on the estimated fair value of the awards on the date of grant.

The Company recognizes stock-based compensation expense for stock option grants with only service conditions on a straight-line basis over the requisite service period of the individual grants, which is generally the vesting period. Generally, stock options fully vest four years from the grant date and have a term of 10 years.

The Company recognizes the effect of forfeitures in stock-based compensation expense based on actual forfeitures when they occur.

The fair value of the shares of common stock underlying stock options has historically been determined by the board of directors (the "Board"), with input from management and contemporaneous third-party valuations, as there was no public market for the common stock. Given the absence of a public trading market for the Company's common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, the Board exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's common stock at each option grant date.

Income Taxes—The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If it is determined that the Company would be able to realize these deferred tax assets in the future in excess of their net recorded amount, an adjustment would be made to the deferred tax asset valuation allowance, which would reduce the income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process: (1) determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

Accounting Standards Updates - Recently Adopted—In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. The Company has adopted ASU 2023-09 for the year ended December 31, 2025 and has retrospectively applied the disclosures for the year ended December 31, 2024. The adoption of ASU 2023-09 had no impact to the Company's financial position, results of operations, or cash flows.

Accounting Standards Updates - Not Yet Adopted—In November 2024, the FASB issued *ASU 2024-03*, *Income Statement—Reporting Comprehensive Income (Subtopic 220-40): Expense Disaggregation Disclosures*. This update requires entities to disaggregate operating expenses into specific categories, such as salaries and wages, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. Accounting Standards Update 2024-03 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. Accounting Standards Update 2024-03 may be applied retrospectively or prospectively. The Company is evaluating the disclosure requirements related to the new standard.

In September 2025, the FASB issued *ASU 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Accounting for and Disclosure of Software Costs* ("ASU 2025-06"), which amends certain aspects of the accounting for and disclosure of internal-use software costs. ASU 2025-06 is effective for annual reporting periods beginning with the year ending December 31, 2028, with early adoption permitted. The Company is evaluating the effect that adoption of ASU 2025-06 will have on its financial statements and related disclosures.

The Company does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on our financial statements or disclosures.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair value.

The Company measures fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The Company utilizes a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1—Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access.
- Level 2—Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.
- Level 3—Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Cash and cash equivalents consist primarily of money market funds, which are measured at fair value using quoted prices in active markets and are therefore classified as Level 1 within the fair value hierarchy. The carrying values of the Company's prepaid expenses, accounts payable and accrued expenses approximate their fair values due to their relatively short maturity periods. The Company has elected the fair value option for its convertible notes, which are remeasured at fair value at each reporting date, and classified within Level 3 of the fair value hierarchy because the valuation incorporates significant unobservable inputs, including assumptions regarding expected timing and probability of financing and liquidity events, market participant discount rates, and instrument-specific credit risk. Warrant liabilities are also measured at fair value on a recurring basis and are classified within Level 3 of the fair value hierarchy because their valuation similarly incorporates significant unobservable inputs.

There were no transfers between fair value measurement levels during the years ended December 31, 2025 and 2024.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis for recognition or disclosure purposes as of December 31, 2025 and December 31, 2024 by level within the fair value hierarchy.

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 458,038	$ —	$ —	$ 458,038
Total assets	$ 458,038	$ —	$ —	$ 458,038
Liabilities:				
Convertible notes	$ —	$ —	$ 8,492,726	$ —
Warrants	—	—	3,183,628	—
Total liabilities	$ —	$ —	$11,676,354	$ —

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$2,013,076	$ —	$ —	$2,013,076
Total assets	$2,013,076	$ —	$ —	$2,013,076
Liabilities:				
Convertible notes	$ —	$ —	$ 2,462,714	$ —
Warrants	—	—	863,694	—
Total liabilities	$ —	$ —	$ 3,326,408	$ —

The convertible notes and warrant liabilities are classified within Level 3 of the fair value hierarchy because their valuations incorporate significant unobservable inputs. Refer to Note 2, Summary of Significant Accounting Policies, for a discussion of the valuation methodologies and significant assumptions used in estimating fair value.

The following table presents the changes in the Company's Level 3 financial liabilities measured at fair value on a recurring basis as of December 31, 2024 and 2025:

Fair Value of Liabilities	Convertible Notes	Warrants
Balance at December 31, 2023	$ —	$ —
Initial recognition at fair value	1,950,547	799,453
Change in fair value	512,168	64,241
Balance at December 31, 2024	$ 2,462,714	$ 863,694
Initial recognition at fair value	3,115,541	80,634
Exchange of 2024 Notes to 2025 Notes	1,501,535	—
Change in fair value	1,412,937	2,239,300
Balance at December 31, 2025	$ 8,492,726	$3,183,628

Because the convertible notes and warrants are accounted for as separate units of account and each measured at fair value, the aggregate fair value of the instruments issued at inception exceeded the cash proceeds received. As a result, the Company recognized a loss at issuance for the convertible notes within non-operating expense, net. The aggregate initial fair value of the convertible notes and warrants issued during the year ended December 31, 2024 exceeded the cash proceeds received by $516,635, resulting in a $366,444 loss was recorded in the change in fair value of notes and a $150,191 loss was recorded within change in fair value of warrants within non-operating expense, net upon issuance in the accompanying statements of operations and comprehensive loss. The aggregate initial fair value of the convertible notes and warrants issued during the year ended December 31, 2025 exceeded the cash proceeds received by $1,560,240, resulting in a $1,520,880 loss was recorded in the change in fair value of notes and a $39,360 loss was recorded within change in fair value of warrants within non-operating expense, net upon issuance in the accompanying statements of operations and comprehensive loss.

The following table presents the significant assumptions related to the fair value for the convertible notes and warrants for the years ended December 31, 2025 and 2024:

	2025	2024
Time to Next Equity Financing (in years)	0.00 - 1.53	1.78 - 2.00
Probability of Next Equity Financing	0.0 - 60.0%	30.0%
Discount rate	37.0 - 38.4%	36.6 - 36.8%

4. BALANCE SHEET COMPONENTS

Prepaid Expenses

Prepaid expenses consist of the following as of December 31:

	2025	2024
Prepaid research and development expenses	$127,317	$ 84,008
Prepaid clinical study expenses	74,438	75,938
Prepaid insurance	51,684	52,074
Other prepaid expenses	76,991	57,876
Total	$330,430	$269,896

Accrued Expenses

Accrued expenses consist of the following as of December 31:

	2025	2024
Accrued research and development expenses	$273,503	$637,105
Accrued professional services	155,704	14,450
Accrued other liabilities	20,000	21,613
Total	$449,207	$673,168

5. CONVERTIBLE NOTES AND WARRANTS

In October 2024, the Company entered into a Convertible Note and Warrant Purchase Agreement pursuant to which it issued convertible promissory notes with an aggregate principal balance of $2,750,000 (the “2024 Convertible Notes”), which had a contractual maturity date of October 11, 2026. Accordingly, the 2024 Convertible Notes were classified as non-current liabilities in the accompanying balance sheet as of December 31, 2024. The 2024 Convertible Notes accrue interest at 4.21% per annum and were convertible into equity securities of the Company upon the occurrence of certain financing, liquidity, maturity, and other specified events. Concurrently with the issuance of the 2024 Convertible Notes, the Company issued freestanding warrants to purchase equity securities of the Company. The Company elected the fair value option under ASC 825 for the 2024 Convertible Notes upon issuance. Accordingly, the 2024 Convertible Notes were recorded at fair value at issuance and remeasured to fair value at each reporting date, with changes in fair value recognized in earnings. The Company has elected to report changes in fair value attributable to the accrual of contractual interest as part of the overall change in fair value recognized in earnings. Because the 2024 Convertible Notes and warrants are accounted for as separate units of account and each measured at fair value, the aggregate fair value of the instruments issued at inception exceeded the cash proceeds received. As a result, the Company recognized a loss at issuance within non-operating expense. The aggregate initial fair value of the 2024 Convertible Notes and warrants exceeded the cash proceeds received by $516,635, resulting in a $366,444 loss was recorded in the change in fair value of notes and a $150,191 loss was recorded within change in fair value of warrants within non-operating expense net upon issuance.

June 2025 Exchange

In June 2025, the Company exchanged the outstanding 2024 Convertible Notes for newly issued convertible notes (the "June 2025 Exchange"). The amended instruments (the "2025 Convertible Notes") modified several key economic terms, including increasing the financing-event payout multiple from 1.0x to 1.43x, increasing the liquidation-event payout multiple from 3.0x to 4.0x, revising conversion mechanics through the introduction of valuation cap and discount-based features, and modifying certain conversion and liquidation participation rights.

The Company evaluated the June 2025 Exchange under ASC 470-50 and concluded that the amendments significantly modified the economics of the 2024 Convertible Notes, including revised financing and liquidation payout multiples, revised conversion pricing mechanics and enhanced participation rights. Accordingly, the June 2025 Exchange was accounted for as an extinguishment under ASC 470-50.

In connection with the June 2025 Exchange, the Company recognized a loss on exchange of $1,501,535 representing the difference between the fair value of the 2025 Convertible Notes and the carrying value of the 2024 Convertible Notes. The Company concluded that the 2025 Convertible Notes remained eligible for the fair value option as the amended conversion feature did not represent a substantial premium under ASC 825 and elected the fair value option upon initial recognition for all 2025 Convertible Notes, including those issued in the June 2025 Exchange and those issued to investors in separate financing transactions. Accordingly, the Company continued to apply the fair value option and no portion of the 2025 Convertible Notes were classified within stockholders' deficit.

Subsequent Amendments and February 2026 Exchange

Following the June 2025 Exchange, the Company entered into a series of amendments to the 2025 Convertible Notes and related warrants. These amendments primarily consisted of maturity extensions to the 2025 Convertible Notes. The Company concluded that these amendments did not introduce new settlement outcomes or fundamentally change the economic characteristics of the 2025 Convertible Notes and therefore accounted for such amendments as modifications. Accordingly, the existing carrying value of the 2025 Convertible Notes was retained and no gain or loss was recognized as a result of the modifications. As of December 31, 2025, the 2025 Convertible Notes had a contractual maturity date of January 31, 2026 and were therefore classified as current liabilities in the accompanying balance sheet.

In February 2026, in connection with the Company's broader recapitalization and bridge financing transaction, the Company exchanged the outstanding 2025 Convertible Notes for newly issued 2026 Convertible Notes. The exchange primarily extended the maturity of the 2025 Convertible Notes while maintaining substantially similar payout structures and economic characteristics. The Company concluded that the exchange did not result in a fundamental change to the nature of the instrument and therefore accounted for the exchange as a modification. Accordingly, the existing carrying value of the 2025 Convertible Notes was retained, no extinguishment accounting was applied, and no gain or loss was recognized as a result of the modification. The Company concluded that the 2026 Convertible Notes remained eligible for the fair value election under ASC 825 and were designated at fair value upon initial recognition. The 2026 Convertible Notes were accounted for as a continuation of the 2025 Convertible Notes. Accordingly, any fees or other amounts exchanged directly between the Company and the noteholders as part of the modification adjusted the carrying amount of the 2025 Convertible Notes and third-party costs were recognized as expense as incurred.

Warrants

The warrants issued in connection with the convertible note financings are freestanding financial instruments. The warrants are exercisable for equity securities of the Company and are classified as liabilities under ASC 480 because they are exercisable into preferred stock that contains redemption features not solely within the Company's control. Accordingly, the warrants are recorded as liabilities at fair value upon issuance and are subsequently remeasured at fair value at each reporting date, with changes in fair value recognized in earnings.

In October 2025, the Company amended certain warrant terms, including increasing warrants associated with the outstanding convertible notes. The amendment increased the fair value of the warrant liabilities. The Company concluded that the amendment did not significantly modify the economic characteristics of the related convertible notes.

During the year ended December 31, 2024, the Company recognized a $512,168 loss related to changes in the fair value of 2024 Convertible Notes and a $64,241 loss related to changes in the fair value of warrant liabilities. During the year ended December 31, 2025, the Company recognized a $1,412,937 loss related to the changes in fair value of convertible notes, $1,501,535 loss on the exchange of the 2024 Convertible Notes for 2025 Convertible Notes, and a $2,239,300 loss related to changes in the fair value of warrant liabilities. All such amounts were recorded within non-operating expense in the Company's statements of operations and comprehensive loss.

The following table presents the aggregate unpaid principal balance of the Convertible Notes compared with their aggregate fair value as of each balance sheet date, including the excess (deficit) of fair value over unpaid principal:

	December 31, 2025	December 31, 2024
Convertible notes - fair value	$ 8,492,726	$ 2,462,714
Unpaid convertible notes principal	(5,946,175)	(2,750,000)
Fair value excess (deficit) over unpaid principal	$ 2,546,551	$ (287,286)

6. CONVERTIBLE PREFERRED STOCK

The Company has issued five series of Convertible Preferred Stock, Series A through Series E.

Series A Extinguishment

On October 7, 2024, the Company entered into a Fourth Amended and Restated Voting Agreement and amended its certificate of incorporation to modify the governance rights associated with its Series A Preferred Stock. The amendments removed certain rights previously granted to Series A holders, including (i) the right to elect a member of the Board of Directors and (ii) enhanced voting rights that provided Series A holders with disproportionate voting power relative to their economic ownership (including the elimination of the "special voting" structure under which Series A holders had significantly greater voting power on an as-converted basis). The holders were not compensated for the removal for their special voting rights.

The Company evaluated the amendment under the applicable guidance for preferred stock modifications and extinguishments and concluded that the removal of these governance and control rights represented a substantive change to the terms of the instrument, as the amendments significantly reduced the relative voting power and governance influence of Series A holders, despite no changes to the underlying economic terms. Accordingly, the amendment was accounted for as an extinguishment of the existing Series A Preferred Stock and the issuance of new Series A Preferred Stock.

The fair value of the modified Series A Preferred Stock immediately following the amendment was estimated to be $17,813,805, based on a contemporaneous valuation of the Company's equity, compared to a carrying amount of $20,197,475 immediately prior to the amendment. As a result, the Company recognized a deemed dividend of $2,383,670, representing the reduction in the carrying value of the Series A Preferred Stock and the resulting transfer of value to the remaining equity holders. The deemed dividend was recorded as a reduction to accumulated deficit. No changes were made to the liquidation preferences, dividend rights, conversion rights, or other economic terms of the Series A Preferred Stock as part of the amendment; rather, the amendment exclusively impacted governance and voting rights.

Reverse Stock Split

In February 2026, the Company effected a 1-for-10 reverse stock split of its common stock and preferred stock in connection with a broader recapitalization transaction (see Note 11 – Subsequent Events for further details). All share and per share amounts presented in the accompanying financial statements and related notes have been retrospectively adjusted to reflect the reverse stock split for all periods presented. The reverse stock split did not affect the par value of the Company's common stock or preferred stock.

The following table summarizes the authorized, issued, and outstanding Convertible Preferred Stock as of December 31, 2025 (reflecting the 1-for-10 reverse stock split effected in February 2026):

Class	Year of Issuance	Issuance Price per Share	Shares Authorized	Shares Issued and Outstanding	Total Proceeds or Exchange Value	Issuance Costs	Net Proceeds	Liquidation Price per Share
Series A	2013	$ 0.40	2,525,000	2,525,000	$ 1,010,000	$ —	$ 1,010,000	$ 0.40
Series B	2015	8.00	1,250,000	1,250,000	10,000,000	—	10,000,000	8.00
Series C	2015 - 2016	13.30	3,529,420	3,529,413	46,941,193	247,480	46,693,713	13.30
Series D	2018 and 2020	13.30	2,037,245	1,414,345	18,810,789	278,573	18,532,216	13.30
Series E	2021	13.40	4,241,659	2,117,253	28,371,190	216,950	28,154,240	13.40
			13,583,324	10,836,011	$105,133,172	$743,003	$104,390,169	

The powers, preferences, rights, qualifications, limitations, and restrictions of the shares of Convertible Preferred Stock are as follows:

Dividends

Dividends shall accrue to holders of the Convertible Preferred Stock at the rate of 8% of the original issue price for the applicable series of Convertible Preferred Stock per annum subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization, reclassification and other similar events payable only when, and if, declared by the Board. The right to receive dividends on Convertible Preferred Stock are not cumulative, and therefore, if not declared in any year, the right to such dividends shall terminate and shall not carryforward into the next year. There have been no dividends declared to date.

Liquidation Rights

In the event of any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary or a deemed liquidation event (which includes a merger, the sale of all of the Company's assets, or a change of control) the holders of the Convertible Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to stockholders, pari passu, at a liquidation price per share equal to the greater of: (1) the initial liquidation price of such Convertible Preferred Stock, plus any declared and unpaid dividends or (2) an amount that would have been payable had all the shares of the Convertible Preferred Stock been converted into the common stock. These payments will be made to or set aside prior to the holders of shares of any other class or series of capital stock that is not, by its terms, senior to the Convertible Preferred Stock.

Voting Rights

The holders of shares of Convertible Preferred Stock shall be entitled to vote together with the holders of Common Stock on all matters submitted to a vote of stockholders and shall vote as a single class on an as-converted basis, except as otherwise required by applicable law or the Company's Certificate of Incorporation.

Effective October 7, 2024, the Company amended its Certificate of Incorporation and related governance documents to eliminate the enhanced voting rights previously associated with the Series A Convertible Preferred Stock, including the special voting structure and the right of the holders of Series A Convertible Preferred Stock to designate a member of the Board of Directors. Following such amendment, the Series A Convertible Preferred Stock no longer carries any special voting or governance rights beyond those applicable to the Company's other series of Convertible Preferred Stock.

Conversion

Each share of Convertible Preferred Stock is convertible, at the option of the holder, at any time into such number of fully paid and nonassessable shares of common stock as is determined by dividing the applicable original issue price of such series of Convertible Preferred Stock by the applicable conversion price then in effect. The conversion price is subject to customary adjustment for stock splits, stock dividends, combinations, recapitalizations, reclassifications and similar events, as provided in the Company's Certificate of Incorporation.

Each share of Convertible Preferred Stock shall automatically convert into common stock upon the occurrence of (i) the closing of the sale of shares of common stock to the public in a firm commitment underwritten public offering meeting the qualifications specified in the Company's Certificate of Incorporation or (ii) the written consent or affirmative vote of the holders of the requisite percentage of the outstanding shares of Convertible Preferred Stock, voting together as a single class on an as-converted basis, as specified in the Company's Certificate of Incorporation.

Following the October 7, 2024 amendment to the Company's Certificate of Incorporation, shares of Series A Convertible Preferred Stock are convertible into Common Stock and no longer carry the special voting rights that were previously associated with such shares. The October 2024 amendment did not modify the economic conversion terms, conversion ratio, or anti-dilution provisions applicable to the Convertible Preferred Stock.

7. EQUITY INCENTIVE PLAN

The Company's 2013 Employee, Director, and Consultant Equity Incentive Plan as amended on October 20, 2020 (the "Plan") was originally adopted by its Board and stockholders in April 2013. As of December 31, 2025 and 2024, a total of 4,150,000 and 3,750,000 shares of common stock, respectively, were reserved for issuance under the Plan. As of December 31, 2025 and 2024, 320,703 and 3,521 common shares, respectively, remain available for issuance under the Plan.

Stock Option Activity—Each stock option grant carries varying vesting schedules, which are generally four years. Each stock option shall terminate not more than 10 years from the date of the grant.

A summary of the stock option activity under the Plan is presented in the table below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2024	1,848,274	$ 5.42	7.6	$ 23,579
Granted	1,608,679	3.30		
Exercised	(7,500)	0.40		
Forfeited	(52,549)	3.80		
Expired	(48,175)	4.86		
Outstanding at December 31, 2024	3,348,729	$ 4.45	7.8	907,571
Options exercisable at December 31, 2024	3,287,649	$ 4.47	7.8	868,855
Vested and expected to vest at December 31, 2024	3,348,729	$ 4.45	7.8	907,571
Outstanding at January 1, 2025	3,348,729	$ 4.45	7.8	$ 907,571
Granted	275,000	2.90		
Exercised	—	—		
Forfeited	(46,773)	3.08		
Expired	(145,407)	4.86		
Outstanding at December 31, 2025	3,431,549	$ 4.32	6.3	$1,111,572
Options exercisable at December 31, 2025	3,174,823	$ 4.44	6.0	$ 883,162
Vested and expected to vest at December 31, 2025	3,431,549	$ 4.32	6.3	$1,111,572

The Company received cash proceeds from the exercise of stock options of $0 and $3,000 during the years ended December 31, 2025 and 2024, respectively. The total intrinsic value (the amount by which the stock price exceeds the exercise price of the stock option on the date of exercise) of the stock options exercised during the years ended December 31, 2025 and 2024, was $0 and $23,250, respectively. The weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024, was $2.78 and $3.00, respectively. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had an exercise price lower than the fair value of the Company's common stock.

The Company utilized the Black-Scholes option-pricing model for determining the estimated fair value of stock options. The Black-Scholes option-pricing model requires the use of subjective assumptions. The assumptions used to value stock option grants for the years ended December 31, 2025 and 2024, were as follows:

	December 31, 2025	December 31, 2024
Fair value of common stock	$3.80	$3.80 - $4.70
Risk-free interest rate	4.40% - 4.41%	3.68% - 4.64%
Expected dividend yield	—	—
Weighted-average expected term	6.0 years	5.2 years
Expected volatility	75%	70% - 75%

Risk-Free Interest Rate—The risk-free interest rate for periods within the expected term of the awards is based on the US Treasury yield curve in effect at the time of the grant.

Expected Dividend Yield—The Company has never declared or paid any cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Expected Term—The Company calculates the expected term using the "simplified" method, which is the simple average of the vesting period and the contractual term. The simplified method is applied as the Company does not have sufficient historical data to provide a reasonable basis for an estimate of the expected term.

Expected Volatility—As the Company has been privately held since inception, there is no specific historical or implied volatility information available. Accordingly, the Company estimates the expected volatility on the historical stock volatility of a group of similar companies that are publicly traded over a period equivalent to the expected term of the stock options.

Exercise Price—The exercise price is taken directly from the grant notice issued to employees and nonemployees.

The Company's stock-based compensation expense is allocated to the following operating expense categories on the statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024, as follows:

	December 31, 2025	December 31, 2024
Research and development	$ 120,451	$ 2,844,357
General and administrative	84,098	3,368,553
Total stock-based compensation expense	$ 204,549	$ 6,212,910

No related tax benefits of the stock-based compensation expense have been recognized and no related tax benefits have been realized from the exercise of stock options due to the Company's net operating loss carryforwards.

Total unrecognized stock-based compensation expense as of December 31, 2025 and 2024, was $579,960 and $147,866, respectively, which will be recognized over the remaining weighted-average vesting period of 2.99 years and 3.01 years, respectively.

8. INCOME TAXES

The Company has not recorded federal or state income taxes during the years ended December 31, 2025 and 2024, as the Company incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

Significant components of the Company's deferred tax assets (liabilities) as of December 31, 2025 and 2024, are as follows:

	Year Ended December 31,	
	2025	2024
Net operating loss carryforwards	25,968,870	24,342,037
Tax credit carryforwards	2,938,454	2,912,251
Capitalized R&D	3,726,022	3,700,537
Nondeductible stock-based compensation	2,266,232	2,361,328
Other	131,464	186,357
Total deferred tax assets	35,031,042	33,502,510
Valuation allowance	(35,031,042)	(33,502,510)
Net deferred tax assets (liability)	—	—

A reconciliation of the income tax at the federal statutory tax rate to the Company's effective income tax rate for the years-ended December 31, 2025 and 2024, is as follows:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Amount	Percent	Amount	Percent
Pretax Income (Loss)	$(11,291,213)		$(10,672,196)	
US Federal Statutory Tax Rate	(2,371,155)	21.0%	(2,241,161)	21.0%
State and Local Income Taxes, net of Fed benefit	—	0.0%	—	0.0%
State Deferred Taxes	(356,784)	3.2%	(609,929)	5.7%
Change in Valuation Allowance	356,784	-3.2%	609,929	-5.7%
Tax Credits:				
Federal R&D Credits	—	0.0%	223,085	-2.1%
Change in valuation allowance	1,171,748	-10.4%	1,846,542	-17.4%
Nontaxable or Nondeductible Items:				
Stock Compensation	117,125	-1.0%	69,049	-0.6%
Change in FV of Warrant Liability	1,082,292	-9.6%	121,046	-1.1%
Other	(10)	0.0%	(18,561)	0.2%
Total	**$ —**	**0.0%**	**$ —**	**0.0%**

The Company's effective tax rate for December 31, 2025 and 2024, differs from the federal statutory tax rate of 21% mainly due to the effect of deferred state income tax benefits resulting from state net operating loss carryforwards and the tax benefits related to research and development tax credits. These benefits to the effective tax rate are fully offset by the increase in the Company's valuation allowance from the prior year.

The future realization of the tax benefits from existing temporary differences and tax attributes ultimately depends on the existence of sufficient taxable income. The Company assesses the realizability of its deferred tax assets at each balance sheet date. In assessing the realization of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the projected future taxable income, expected reversal of existing deferred tax liabilities, and tax planning strategies in making this assessment. After consideration of all available evidence, both positive and negative, the Company determined that it is not more likely than not that its net deferred tax assets will be realized in the foreseeable future. As a result, the Company increased its valuation allowance by $1,528,532 and $2,456,471 as of December 31, 2025 and 2024, respectively.

As of December 31, 2025, the Company had the following tax net operating loss carryforwards available to reduce future federal and Connecticut taxable income, and tax credit carryforwards available to offset future federal and Connecticut income taxes:

	Amount	Expiration
Tax net operating loss carryforwards:		
Federal (pre-2018 NOLs)	34,309,101	2033 - 2037
Federal (post-2017 NOLs)	62,188,794	N/A
Connecticut	96,275,309	2033 - 2045
Tax credit carryforwards:		
Federal research and development	2,315,862	2033 - 2041
Connecticut research and development	785,360	2032 - 2039
Connecticut other	2,731	2026 - 2027

The future realization of the Company's net operating loss carryforwards and other tax attributes may also be limited by the change in ownership rules under the U.S. Internal Revenue Code Section 382. Under Section 382, if a corporation undergoes an ownership change (as defined), the corporation's ability to utilize its net operating loss carryforwards and other tax attributes to offset income may be limited. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes.

The Company records uncertain tax positions as liabilities in accordance with ASC 740-10 and adjusts these liabilities when judgment changes as a result of the evaluation of new information not previously available. Since there is complexity in some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax in the period in which new information is available. The calculation and assessment of the Company's income tax exposures generally involves the uncertainties in the application of complex tax laws and regulations for federal, state, and foreign jurisdictions. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon local tax examination including resolutions of any related appeals or litigation on the basis of the technical merits.

The Company files income tax returns in the US where it is subject to tax examination by local tax authorities. The Company is not currently under examination for income taxes and is not aware of any issues under review that could result in significant payments, accruals or material deviation from its tax positions. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by local tax authorities to the extent utilized in a future period. The statute of limitations for the Company has expired for tax years prior to 2022.

As of December 31, 2025 and 2024, the Company did not have any unrecognized tax benefits. To the extent penalties and interest would be assessed on any underpayment of income tax, the Company's policy is that such amounts would be accrued and classified as a component of income tax in the financial statements. To date, the Company has not recorded any such interest or penalties.

Additionally, as a result of legislation in the State of Connecticut, companies have the opportunity to exchange certain research and development tax credit carryforwards for a cash payment of 90% of the research and development tax credit for the year ended December 31, 2025, and 65% of the research and development tax credit for the year ended December 31, 2024.. The research and development expenses that qualify for Connecticut credits are limited to those costs incurred within Connecticut. The Company has elected to participate in the exchange program and, as a result, has recognized net benefits of $15,120 and $12,822 for the years ended December 31, 2025 and 2024, respectively, which are included in research and development expenses in the accompanying statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the Company has recorded $29,907 and $30,671, respectively, of research and development tax credit receivables in current assets.

For the years ended December 31, 2025 and 2024, there were no income taxes paid (net of refunds received).

On July 4, 2025, the One Big Beautiful Bill Act was enacted into law with changes to U.S. tax law that will be applicable to the Company beginning in 2025. These changes include provisions allowing accelerated tax deductions for qualified property and research expenditures.

9. RELATED-PARTY TRANSACTIONS

No material related-party transactions were identified during the year ended December 31, 2025. During the year ended December 31, 2024, the Company entered into transactions with entities affiliated with certain members of its Board of Directors through those directors' leadership positions and family affiliations. These transactions were conducted in the ordinary course of business and primarily consisted of advisory, administrative and office facility services provided to the Company. During the year ended December 31, 2024, the Company incurred $126,967 of advisory service fees payable to an entity affiliated with a member of the Board of Directors. In addition, the Company incurred $103,181 of administrative service fees and $31,178 of rent expense payable to entities affiliated with another member of the Board of Directors and members of such director's immediate family. While certain of these transactions were not individually material, they have been presented on an aggregate basis as related-party transactions. As of December 31, 2024, amounts due to related parties were approximately $10,000 and are included within accounts payable in the accompanying balance sheets.

10. COMMITMENTS AND CONTINGENCIES

Commitments

The Company sponsors a 401(k) defined contribution plan covering all eligible US employees. Contributions to the 401(k) plan are discretionary. The Company did not make any matching contributions to the 401(k) plan for the years ended December 31, 2025 and 2024.

Contingencies

The Company does not have any outstanding or ongoing litigation and legal matters.

11. SUBSEQUENT EVENTS

In connection with the preparation of the financial statements, the Company evaluated events subsequent to the balance sheet date of December 31, 2025 through July 29, 2026, the date the financial statements were available for issuance.

Rights offering, Recapitalization, and 2026 Bridge Financing

On February 17, 2026, the Company completed a recapitalization transaction in connection with a bridge financing. The transaction included (i) a 1-for-10 reverse stock split, (ii) a rights offering and issuance of senior secured convertible notes, which included approximately $1,233,451 of new financing proceeds and the exchange of previously outstanding notes, (iii) amendments to the Company's Certificate of Incorporation, and (iv) the exchange and conversion of certain outstanding preferred stock. The convertible notes issued in connection with the bridge financing are senior secured, bear interest at 7% per annum, mature on May 31, 2026, and are convertible into equity upon the consummation of a future financing, including at a discount to the financing price or subject to a valuation cap.

In connection with the amended Certificate of Incorporation, holders of preferred stock were required to participate in the bridge financing on a specified pro rata basis in order to retain their preferred stock rights. Holders that participated exchanged their existing preferred stock for newly designated Series 1 Preferred Stock, while holders that did not participate were required to convert their preferred stock into common stock.

Following the reverse stock split, 2,892,376 shares of preferred stock were exchanged for 28,923,760 shares of Series 1 Preferred Stock and 7,943,633 shares of preferred stock were converted into common stock.

In April 2026, the Company issued an additional $10,000,000 of senior secured convertible promissory notes. The additional notes were issued on substantially the same terms as the notes issued in February 2026.

Merger Agreement

On May 17, 2026, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Quince Therapeutics, Inc. ("Quince"), Phoenix Merger Sub I, Inc., Phoenix Merger Sub II, LLC and Orphai Holdings Therapeutics, Inc., pursuant to which the Company was acquired by Quince. Under the terms of the Merger Agreement, Merger Sub I merged with and into Orphai Holdings Therapeutics, Inc., with Orphai Holdings Therapeutics, Inc. surviving as a wholly owned subsidiary of Quince, followed immediately by the merger of Orphai Holdings Therapeutics, Inc. with and into Merger Sub II, pursuant to which Merger Sub II was the surviving entity.

Pursuant to the Merger Agreement, holders of Orphai equity securities received an aggregate of 3,258,517 shares of Quince common stock and 67,101.2355 shares of Quince Series C Non-Voting Convertible Preferred Stock, subject to the terms and conditions set forth in the Merger Agreement. Outstanding Company options and warrants were assumed or exchanged for corresponding Quince equity instruments, and the Company's outstanding convertible notes converted into equity immediately prior to the effective time of the merger in accordance with their terms.

In connection with the execution of the Merger Agreement, Quince entered into securities purchase agreements with certain investors providing for a private placement financing which generated gross proceeds of $115,000,000 through the issuance of Quince Series C Convertible Preferred Stock and related warrants, subject to the satisfaction of customary closing conditions.

Stock Options

In February 2026, the Company created the 2026 Stock Incentive Plan (the "2026 Plan") which was adopted by its Board and stockholders. In May 2026, the Company amended the existing 2026 Plan to increase the shares of common stock reserved for issuance from 6,832,554 shares to 35,000,000 shares.

The Board of Directors authorized the grant of stock options to purchase a total of 34,559,284 shares of common stock to management, employees and select consultants and advisors at a weighted average exercise price of $0.50 per share during the period from January 1, 2026 through July 29, 2026.

* * * * * *

Exhibit 99.7

Orphai Therapeutics, Inc.

Financial Statements as of March 31, 2026 and
December 31, 2025 and for the Quarterly Periods
Ended March 31, 2026 and 2025

ORPHAI THERAPEUTICS, INC.

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ORPHAI THERAPEUTICS, INC.

BALANCE SHEETS
AS OF MARCH 31, 2026 AND DECEMBER 31, 2025
(UNAUDITED)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 430,980	$ 658,248
Deposits	15,000	15,000
Research and development tax credit receivable	—	12,822
Prepaid expenses	246,153	330,430
Miscellaneous receivables	5,100	5,100
Total current assets	**697,233**	**1,021,600**
Total assets	**697,233**	**1,021,600**
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,726,411	$ 1,533,558
Accrued expenses	619,520	449,207
Convertible Notes	10,446,729	8,492,726
Total current liabilities	**12,792,660**	**10,475,491**
Warrants	3,012,238	3,183,628
Total liabilities	**15,804,898**	**13,659,119**
Commitments and contingencies		
Redeemable convertible preferred stock		
Redeemable convertible preferred stock, $0.0001 par value—108,360,317 and 13,583,324 shares authorized as of March 31, 2026 and December 31, 2025, respectively. 28,923,770 and 10,836,011 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively and liquidation preference of $38,620,400 and $105,133,172 as of March 31, 2026 and December 31, 2025, respectively	35,911,831	102,006,774
Stockholders' equity (deficit)		
Common stock, $0.0001 par value—144,923,000 and 22,500,000 shares authorized as of March 31, 2026 and December 31, 2025, respectively. 8,341,383 and 397,753 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	477,810	398
Additional paid-in capital	78,463,435	12,366,487
Accumulated deficit	(129,960,741)	(127,011,178)
Total stockholders' deficit	**(51,019,496)**	**(114,644,293)**
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	**$ 697,233**	**$ 1,021,600**

ORPHAI THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE QUARTERS ENDED MARCH 31, 2026 AND 2025
(UNAUDITED)

	March 31, 2026	March 31, 2025
Operating expenses:		
Research and development	$ 1,410,346	$ 1,451,091
General and administrative	1,008,831	440,162
Total operating expenses	**2,419,177**	**1,891,253**
Loss from operations	**(2,419,177)**	**(1,891,253)**
Nonoperating income (expense):		
Interest income	2,788	14,946
Change in fair value of notes	(946,481)	(128,880)
Change in fair value of warrants	397,318	84,560
Other income, net	15,989	16,028
Total nonoperating expense	**(530,386)**	**(13,346)**
Net loss and comprehensive loss	**$(2,949,563)**	**$(1,904,599)**

ORPHAI THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
FOR THE QUARTERS ENDED MARCH 31, 2026 AND 2025
(UNAUDITED)

	Redeemable Convertible Preferred Stock		Stockholders' Deficit				
			Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
December 31, 2024	**10,836,011**	**$102,006,774**	**397,749**	**$ 398**	**$ 12,161,938**	**$ (115,719,965)**	**$ (103,557,629)**
Common stock issued upon exercise stock options	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	42,421	—	42,421
Net loss	—	—	—	—	—	(1,904,599)	(1,904,599)
March 31, 2025	**10,836,011**	**$102,006,774**	**397,749**	**$ 398**	**$ 12,204,359**	**$ (117,624,564)**	**$ (105,419,807)**
December 31, 2025	**10,836,011**	**$102,006,774**	**397,749**	**$ 398**	**$ 12,366,487**	**$ (127,011,178)**	**$ (114,644,293)**
Issuance of common stock for the conversion of preferred shares	(7,943,633)	(66,094,943)	7,943,634	477,412	65,617,532	—	66,094,944
Exchange of Series C preferred shares for Series 1-C preferred shares	(803,080)	—	—	—	—	—	—
Exchange of Series D preferred shares for Series 1-D preferred shares	(571,426)	—	—	—	—	—	—
Exchange of Series E preferred shares for Series 1-E preferred shares	(1,517,872)	—	—	—	—	—	—
Issuance of Series 1-C Preferred shares for the conversion of Series C Preferred shares	8,030,790	—	—	—	—	—	—
Issuance of Series 1-D Preferred shares for the conversion of Series D Preferred shares	5,714,250	—	—	—	—	—	—
Issuance of Series 1-E Preferred shares for the conversion of Series E Preferred shares	15,178,730	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	479,416	—	479,416
Net loss	—	—	—			(2,949,563)	(2,949,563)
March 31, 2026	**28,923,770**	**$ 35,911,831**	**8,341,383**	**$477,810**	**$ 78,463,435**	**$ (129,960,741)**	**$ (51,019,496)**

ORPHAI THERAPEUTICS, INC.

STATEMENT OF CASH FLOWS
FOR THE QUARTERS ENDED MARCH 31, 2026 AND 2025
(UNAUDITED)

	March 31, 2026	March 31, 2025
Cash flows from operating activities:		
Net loss	$(2,949,563)	$(1,904,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	—	347
Change in fair value of convertible notes and warrants	549,163	44,320
Stock-based compensation expense	479,416	42,421
Changes in operating assets and liabilities:		
Prepaid expenses	84,277	52,842
R&D tax credit receivable	12,822	—
Accounts payable	192,853	245,074
Accrued expenses	170,313	540,326
Net cash used in operating activities	(1,460,719)	(979,269)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes	1,233,451	—
Net cash provided by financing activities	1,233,451	—
Net decrease in cash and cash equivalents	(227,268)	(979,269)
Cash and cash equivalents, beginning of year	658,248	2,220,979
Cash and cash equivalents, end of year	$ 430,980	$ 1,241,710

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Orphai Therapeutics, Inc. (the "Company"), formerly known as AI Therapeutics, Inc., and LAM Therapeutics, Inc., was incorporated as a Delaware corporation on March 4, 2013. 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. The Company is currently developing LAM-001 for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD), bronchiolitis obliterans syndrome (BOS), and sarcoidosis associated pulmonary hypertension (SAPH).

Liquidity and Going Concern—The accompanying financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since its inception, the Company has generated no revenue and has funded its operations primarily through the issuance of preferred stock and convertible promissory notes to private investors. The Company has incurred recurring operating losses and negative cash flows from operations since inception, including a net loss of $2,949,563 for the three months ended March 31, 2026, and had an accumulated deficit of $129,960,741 as of March 31, 2026. The Company expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future as it continues to advance its research and development activities.

The Company's existing cash and cash equivalents were not sufficient to fund its planned operations and satisfy its obligations as they became due for a period of at least twelve months from the date these financial statements are available to be issued. Accordingly, management determined that conditions existed that raised substantial doubt about the Company's ability to continue as a going concern.

In order to mitigate these conditions, on May 18, 2026, the Company was acquired by Quince Therapeutics, Inc. ("Quince"). Concurrent with the closing of the merger, Quince completed a private placement financing that generated gross proceeds of approximately $115,000,000 through the issuance of Quince Series C Convertible Preferred Stock and related warrants (see Note 10, Subsequent Events). In connection with the merger, holders of the Company's equity securities received Quince common stock and Quince Series C Convertible Preferred Stock, the Company's outstanding convertible notes converted into equity immediately prior to the effective time of the Merger in accordance with their terms, and the Company's outstanding options and warrants were assumed or exchanged for corresponding Quince equity instruments.

The Quince Series C Convertible Preferred Stock issued in the merger and the private placement financing are convertible into Quince common stock upon receipt of the requisite stockholder approval under applicable Nasdaq listing rules. Under the terms of the Certificate of Designation, if Quince fails to obtain the required stockholder approval or otherwise fails to timely deliver shares of common stock upon conversion following the applicable trigger date, which is the date on which the Series C Preferred

Stock becomes convertible following receipt of the required stockholder approval, holders of the Series C Convertible Preferred Stock are entitled to require Quince to make cash payments based on the 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 the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within the Company's control. Management's plan to convert the Series C Convertible Preferred Stock into common stock and therefore remove the requirement to make cash payment based on the value of the undelivered shares is the execution of a stockholder proxy vote set to take place in or around September 2026. 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 financial statements do not include any adjustments relating to the recoverability and classification of recorded assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation—The accompanying financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2025. These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

Reverse Stock Split—In February 2026, the Company effected a 1-for-10 reverse stock split of its common stock. Accordingly, all stockholders of record received one issued and outstanding common share in exchange for ten outstanding common shares. No fractional shares were issued in connection with the reverse split, and any fractional shares were rounded to the nearest whole share. All share and per-share amounts in these financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents. At March 31, 2026 and December 31, 2025, substantially all the Company's cash and cash equivalents were invested in money market funds at one financial institution. The Company also maintains balances in various operating accounts above federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Use of Estimates—The preparation of the financial statements in conformity with US GAAP requires the Company to make estimates and assumptions about future events that affect the amounts reported in its financial statements and accompanying notes. Future events and their effects cannot be determined with certainty. On an ongoing basis, management evaluates these estimates and assumptions. Significant estimates and assumptions include assumptions underlying the fair value used in the calculation of the stock-based compensation, the fair value of warrants and fair values of convertible notes. In addition, management makes assumptions related to work completed but not yet billed by third party vendors to calculate prepaid and accrued expenses.

Cash and Cash Equivalents—All highly liquid investments purchased with a maturity of three months or less are cash equivalents. As of March 31, 2026 and December 31, 2025, cash and cash equivalents consist of bank depository accounts and money market funds.

Research and Development Tax Credit Receivable—Research and development tax credit receivable includes monies to be received from the State of Connecticut for research and development tax credits. These research and development tax credits are exchanged for a cash refund and are typically collected within one year from the date the tax return is filed with the state. The credits are recognized as an offset to research and development expenses in the statements of operations and comprehensive loss in the annual period the corresponding expenses were incurred.

Research and Development—Research and development expenses are composed of costs incurred in performing research and development activities, including personnel salaries, benefits, and equity-based compensation; external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; the cost of developing and manufacturing clinical study materials, program regulatory costs, expenses associated with obligations under asset acquisitions, license agreements, and other direct and indirect costs. Costs incurred in connection with research and development activities are expensed as incurred. Costs are considered incurred based on an evaluation of the progress to completion of each contract using information and data provided by the respective vendors, including the Company's clinical sites. Depending upon the timing of invoicing by the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid expenses or accrued expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Convertible Notes and Warrant Liabilities—The Company has elected the fair value option under Accounting Standards Codification ("ASC 825"), Financial Instruments, for its convertible notes. The fair value option was elected because the convertible notes contain embedded features and contingent settlement provisions that could otherwise require bifurcation and separate accounting. The election results in a single measurement attribute for the entire convertible notes and eliminates the need to separately account for embedded features and contingent settlement provisions. Accordingly, transaction costs incurred upon issuance of the convertible notes are recognized as incurred in the statements of operations and comprehensive loss.

Convertible notes are initially measured at fair value upon issuance and subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in the statements of operations and comprehensive loss within non-operating expense. The Company has elected to report changes in fair value attributable to the accrual of contractual interest as part of the overall change in fair value recognized in earnings. Accordingly, contractual interest is not presented separately as interest expense.

The fair value of the convertible notes is estimated using scenario-based valuation techniques that considered the probability of financing, conversion, redemption and other settlement scenarios. Significant assumptions include the expected timing and probability of such scenarios, market participant discount rates, contractual terms and other relevant market participant assumptions. Changes in fair value, including those attributable to changes in instrument-specific credit risk, are recognized in the period incurred. Because the valuation incorporates significant unobservable inputs, the fair value measurement of the convertible notes is classified within Level 3 of the fair value

hierarchy. The valuation of the convertible notes incorporates market participant assumptions regarding instrument-specific credit risk as one of several unobservable inputs used in estimating fair value. Changes in market participant credit risk remained relatively stable during the periods presented and changes in the fair value of the convertible notes were driven primarily by revisions to probability-weighted financing and liquidity-event assumptions, contractual terms, and expected timing of future events rather than changes in instrument-specific credit risk. Accordingly, the Company concluded that changes attributable solely to instrument-specific credit risk were not material for the changes in fair value for the three months ended March 31, 2025 and March 31, 2026, respectively. Additional information regarding the Company's fair value measurements, including significant assumptions used in the valuation of the convertible notes, is included in Note 3, Fair Value Measurements.

The Company accounts for certain freestanding warrants as liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity, because the warrants are exercisable into preferred stock that is redeemable upon the occurrence of events not solely within the Company's control. Warrant liabilities are initially measured at fair value upon issuance and subsequently remeasured to fair value at each reporting date, with changes in fair value recognized in the statements of operations and comprehensive loss within non-operating expense.

The fair value of the warrant liabilities is determined using valuation methodologies that incorporate probability-weighted financing, conversion, redemption and other liquidity-event scenarios, together with assumptions regarding the expected timing and probability of each scenario, required market participant discount rates and other relevant inputs. Because the valuation incorporates significant unobservable inputs, the fair value measurement of the warrant liabilities is classified within Level 3 of the fair value hierarchy.

Additional information regarding the valuation methodologies, significant assumptions, fair value hierarchy classifications and changes in fair value is included in Note 3, Fair Value Measurements. For the convertible notes, Note 5 also includes the relationship between the aggregate fair value and the unpaid principal balance as required by ASC 825.

Redeemable Convertible Preferred Stock—The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events which are not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "Deemed Liquidation Event"), the redeemable convertible preferred stock may become redeemable. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to its liquidation value because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock is not probable of occurring as of March 31, 2026. Subsequent adjustments to the carrying values of redeemable convertible preferred stocks to the liquidation value will be made only when it becomes probable that such a deemed liquidation event will occur.

Stock-Based Compensation—The measurement of stock-based compensation expense is based on the estimated fair value of the awards on the date of grant.

The Company recognizes stock-based compensation expense for stock option grants with only service conditions on a straight-line basis over the requisite service period of the individual grants, which is generally the vesting period. Generally, stock options fully vest four years from the grant date and have a term of 10 years.

The Company recognizes the effect of forfeitures in stock-based compensation expense based on actual forfeitures when they occur.

The fair value of the shares of common stock underlying stock options has historically been determined by the board of directors (the "Board"), with input from management and contemporaneous third-party valuations, as there was no public market for the common stock. Given the absence of a public trading market for the Company's common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, the Board exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's common stock at each option grant date.

Income Taxes—The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If it is determined that the Company would be able to realize these deferred tax assets in the future in excess of their net recorded amount, an adjustment would be made to the deferred tax asset valuation allowance, which would reduce the income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process: (1) determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

Accounting Standards Updates - Recently Adopted—In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. The Company has adopted ASU 2023-09 for the year ended December 31, 2025. The adoption of ASU 2023-09 had no impact to the Company's financial position, results of operations, or cash flows.

Accounting Standards Updates - Not Yet Adopted—In November 2024, the FASB issued *ASU 2024-03*, *Income Statement—Reporting Comprehensive Income (Subtopic 220-40): Expense Disaggregation Disclosures*. This update requires entities to disaggregate operating expenses into specific categories, such as salaries and wages, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. Accounting Standards Update 2024-03 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. Accounting Standards Update 2024-03 may be applied retrospectively or prospectively. The Company is evaluating the disclosure requirements related to the new standard.

In September 2025, the FASB issued *ASU 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Accounting for and Disclosure of Software Costs* ("ASU 2025-06"), which amends certain aspects of the accounting for and disclosure of internal-use software costs. ASU 2025-06 is effective for annual reporting periods beginning with the year ending December 31, 2028, with early adoption permitted. The Company is evaluating the effect that adoption of ASU 2025-06 will have on its financial statements and related disclosures.

The Company does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on our financial statements or disclosures

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair value.

The Company measures fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The Company utilizes a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1—Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access.
- Level 2—Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.
- Level 3—Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Cash and cash equivalents consist primarily of money market funds, which are measured at fair value using quoted prices in active markets and are therefore classified as Level 1 within the fair value hierarchy. The carrying values of the Company's prepaid expenses, accounts payable and accrued expenses approximate their fair values due to their relatively short maturity periods. The Company has elected the fair value option for its convertible notes, which are remeasured at fair value at each

reporting date, and classified within Level 3 of the fair value hierarchy because the valuation incorporates significant unobservable inputs, including assumptions regarding expected timing and probability of financing and liquidity events, market participant discount rates, and instrument-specific credit risk. Warrant liabilities are also measured at fair value on a recurring basis and are classified within Level 3 of the fair value hierarchy because their valuation similarly incorporates significant unobservable inputs.

There were no transfers between fair value measurement levels during the period ended March 31, 2026.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis for recognition or disclosure purposes as of March 31, 2026 and December 31, 2025 by level within the fair value hierarchy.

	March 31, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$244,340	$ —	$ —	$ 244,340
Total assets	$244,340	$ —	$ —	$ 244,340
Liabilities:				
Convertible notes	$ —	$ —	$10,446,729	$10,446,729
Warrants	—	—	$ 3,012,238	3,012,238
Total liabilities	$ —	$ —	$13,458,967	$13,458,967

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$458,038	$ —	$ —	$ 458,038
Total assets	$458,038	$ —	$ —	$ 458,038
Liabilities:				
Convertible notes	$ —	$ —	$ 8,492,726	$ 8,492,726
Warrants	—	—	$ 3,183,628	3,183,628
Total liabilities	$ —	$ —	$11,676,354	11,676,354

The convertible notes and warrant liabilities are classified within Level 3 of the fair value hierarchy because their valuations incorporate significant unobservable inputs. Refer to Note 2, Summary of Significant Accounting Policies, for a discussion of the valuation methodologies and significant assumptions used in estimating fair value.

The following table presents the changes in the Company's Level 3 financial liabilities measured at fair value on a recurring basis as of March 31, 2025 and March 31, 2026:

Fair Value of Liabilities	Convertible Notes	Warrants
Balance at December 31, 2024	$ 2,462,714	$863,694
Change in fair value	128,880	(84,560)
Balance at March 31, 2025	$ 2,591,595	$779,134

Fair Value of Liabilities	Convertible Notes	Warrants
Balance at December 31, 2025	$ 8,492,726	$3,183,628
Initial recognition at fair value	1,007,522	225,928
Change in fair value	946,481	(397,318)
Balance at March 31, 2026	$ 10,446,729	$3,012,238

Because the convertible notes and warrants, are accounted for as separate units of account and each measured at fair value, the aggregate fair value of the instruments issued at inception exceeded the cash proceeds received. There were no issuances of convertible notes during the quarter ended March 31, 2025. For the convertible notes issued during the quarter ended March 31, 2026, the Company recognized a loss at issuance within non-operating expense, net. The aggregate initial fair value of the convertible notes and warrants exceeded the cash proceeds received by $708,618, which a $578,822 loss was recorded in the change in fair value of notes and a $129,796 loss was recorded within change in fair value of warrants within non-operating expense, net upon issuance in the accompanying statements of operations and comprehensive loss.

The following table presents the significant assumptions related to the change in fair value for the Convertible Notes and Warrants for the three months ended March 31, 2026 and March 31, 2025:

	March 31, 2026	March 31, 2025
Time to Next Equity Financing (in years)	0.00 - 0.17	1.53 - 1.78
Probability of Next Equity Financing	0.0 - 75.0%	30.0%
Discount rate	37.2 - 38.6%	36.6 - 38.2%

4. BALANCE SHEET COMPONENTS

Prepaid Expenses

Prepaid expenses consist of the following:

	March 31, 2026	December 31, 2025
Prepaid research and development expenses	$ 76,580	$ 127,317
Prepaid clinical study expenses	68,783	74,438
Prepaid insurance	36,179	51,684
Other prepaid expenses	64,611	76,991
Total	$246,153	$ 330,430

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2026	December 31, 2025
Accrued research and development expenses	$162,752	$ 273,503
Accrued professional services	191,018	155,704
Accrued compensation	241,736	—
Accrued other liabilities	24,014	20,000
Total	$619,520	$ 449,207

5. CONVERTIBLE NOTES AND WARRANTS

In October 2024, the Company entered into a Convertible Note and Warrant Purchase Agreement pursuant to which it issued convertible promissory notes with an aggregate principal balance of $2,750,000 (the “2024 Convertible Notes”), which had a contractual maturity date of October 11, 2026. The notes accrued interest at 4.21% per annum and were convertible into equity securities of the Company upon the occurrence of certain financing, liquidity, maturity, and other specified events. Concurrently with the issuance of the 2024 Convertible Notes, the Company issued freestanding warrants to purchase equity securities of the Company. The Company elected the fair value option under ASC 825 for the 2024 Convertible Notes upon issuance. Accordingly, the 2024 Convertible Notes are recorded at fair value at issuance and remeasured to fair value at each reporting date, with changes in fair value recognized in earnings. The Company has elected to present changes in fair value, including amounts attributable to accrued interest, non-operating expense, net. Because the 2024 Convertible Notes and warrants are accounted for as separate units of account and each measured at fair value, the aggregate fair value of the instruments issued at inception exceeded the cash proceeds received. As a result, the Company recognized a loss within change in fair value of non-operating expense, net. The aggregate initial fair value of the 2024 Convertible Notes and warrants exceeded the cash proceeds received by $516,635, which a $366,444 loss was recorded in the change in fair value of notes and a $150,191 loss was recorded within change in fair value of warrants within non-operating expense net upon issuance.

June 2025 Exchange

In June 2025, the Company exchanged the outstanding 2024 Convertible Notes for newly issued convertible notes (the "June 2025 Exchange"). The amended instruments (the "2025 Convertible Notes") modified several key economic terms, including increasing the financing-event payout multiple from 1.0x to 1.43x, increasing the liquidation-event payout multiple from 3.0x to 4.0x, revising conversion mechanics through the introduction of valuation cap and discount-based features, and modifying certain conversion and liquidation participation rights.

The Company evaluated the June 2025 Exchange under ASC 470-50 and concluded that the amendments significantly modified the economics of the Convertible Notes, including revised financing and liquidation payout multiples, revised conversion pricing mechanics and enhanced participation rights. Accordingly, the June 2025 Exchange was accounted for as an extinguishment under ASC 470-50.

In connection with the June 2025 Exchange, the Company recognized a loss on exchange of $1,501,535 representing the difference between the fair value of the 2025 Convertible Notes and the carrying value of the 2024 Convertible Notes. The Company concluded that the 2025 Convertible Notes remained eligible for the fair value option under ASC 825 as the amended conversion feature did not represent a substantial premium and elected the fair value option upon initial recognition for all 2025 Convertible Notes, including those issued in the June 2025 Exchange and those issued to investors in separate financing transactions. Accordingly, the Company continued to apply the fair value option, and no portion of the instruments was classified within stockholders' deficit. The 2025 Convertible Notes were accounted for as a continuation of the 2024 Convertible Notes. Accordingly, any fees or other amounts exchanged directly between the Company and the noteholders as part of the modification adjusted the carrying amount of the Convertible Notes and third-party costs were recognized as expense as incurred. As of December 31, 2025, the 2025 Convertible Notes had a contractual maturity date of January 31, 2026 and were therefore classified as current liabilities in the accompanying balance sheet.

Subsequent Amendments and February 2026 Exchange

Following the June 2025 Exchange, the Company entered into a series of amendments to the convertible notes and related warrants. These amendments primarily consisted of maturity extensions and modifications to warrant coverage. The Company concluded that these amendments did not introduce new settlement outcomes or fundamentally change the economic characteristics of the convertible notes and therefore accounted for such amendments as modifications. Accordingly, the existing carrying value of the 2025 Convertible Notes was retained and no gain or loss was recognized as a result of the modifications.

In February 2026, in connection with the Company's broader recapitalization and bridge financing transaction, the Company exchanged the outstanding 2025 Convertible Notes for newly issued 2026 Convertible Notes. The exchange primarily extended the maturity of the 2025 Convertible Notes while maintaining substantially similar payout structures and economic characteristics. The Company concluded that the exchange did not result in a fundamental change to the nature of the instrument and therefore accounted for the exchange as a modification. Accordingly, the existing carrying value of the 2025 Convertible Notes was retained, no extinguishment accounting was applied, and no gain or loss was recognized as a result of the modification. The Company further concluded that the 2026

Convertible Notes remained eligible for the fair value option under ASC 825 and continued to be measured at fair value. The 2026 Convertible Notes were accounted for as a continuation of the 2025 Convertible Notes. Accordingly, any fees or other amounts exchanged directly between the Company and the noteholders as part of the modification adjusted the carrying amount of the Convertible Notes and third-party costs were recognized as expense as incurred.

Although the February 2026 exchange was accounted for as a modification under ASC 470-50, the Company recognized $1,791,881 within the change in fair value of convertible notes included in non-operating expense, net in the accompanying statements of operations for the three months ended March 31, 2026. This amount reflects the difference between the fair value of the 2026 Convertible Notes immediately following the modification and the carrying value of the 2025 Convertible Notes immediately prior to the modification. Following the modification, the 2026 Convertible Notes continued to be measured at fair value under ASC 825, with subsequent changes in fair value recognized in earnings. As of March 31, 2026, the 2026 Convertible Notes had a contractual maturity date of May 31, 2026 and were therefore classified as current liabilities in the accompanying balance sheet

Warrants

The warrants issued in connection with the convertible note financings are freestanding financial instruments. The warrants are exercisable for equity securities of the Company and are classified as liabilities under ASC 480 because they are exercisable into preferred stock that contains redemption features not solely within the Company's control. Accordingly, the warrants are recorded as liabilities at fair value upon issuance and are subsequently remeasured at fair value at each reporting date, with changes in fair value recognized in earnings.

In October 2025, the Company amended certain warrant terms, including increasing warrants associated with the outstanding convertible notes. The amendment increased the fair value of the warrant liabilities. The Company concluded that the amendment did not significantly modify the economic characteristics of the related convertible notes.

During the three months ended March 31, 2025, the Company recognized a $128,880 loss related to changes in the fair value of convertible notes and a $84,560 gain related to changes in the fair value of warrant liabilities. During the three months ended March 31, 2026, the Company recognized a $845,400 gain related to the changes in fair value of convertible notes, $1,791,881 loss on the exchange of the 2025 convertible notes for 2026 convertible notes, and $397,318 gain related to changes in the fair value of warrant liabilities. All such amounts were recorded within non-operating expense in the Company's statements of operations and comprehensive loss.

The following table presents the aggregate unpaid principal balance of the Convertible Notes compared with their aggregate fair value as of each balance sheet date, including the excess of fair value over unpaid principal:

	March 31, 2026	December 31, 2025
Convertible notes - fair value	$ 10,446,729	$ 8,492,726
Unpaid convertible notes principal	(7,179,626)	(5,946,175)
Fair value excess over unpaid principal	$ 3,267,103	$ 2,546,551

6. CONVERTIBLE PREFERRED STOCK

The Company has issued five series of Convertible Preferred Stock, Series A through Series E.

Reverse Stock Split

In February 2026, the Company effected a 1-for-10 reverse stock split of its common stock and preferred stock in connection with a broader recapitalization transaction (see Note 10 – Subsequent Events for further details). All share and per share amounts presented in the accompanying financial statements and related notes have been retrospectively adjusted to reflect the reverse stock split for all periods presented. The reverse stock split did not affect the par value of the Company's common stock or preferred stock.

Rights offering, Recapitalization, and 2026 Bridge Financing

On February 17, 2026, the Company completed a recapitalization transaction in connection with a bridge financing. The transaction included (i) a 1-for-10 reverse stock split, (ii) a rights offering and issuance of senior secured convertible notes, which included approximately $1,233,451 of new financing proceeds and the exchange of previously outstanding notes, (iii) amendments to the Company's Certificate of Incorporation, and (iv) the exchange and conversion of certain outstanding preferred stock. The convertible notes issued in connection with the bridge financing are senior secured, bear interest at 7% per annum, mature on May 31, 2026, and are convertible into equity upon the consummation of a future financing, including at a discount to the financing price or subject to a valuation cap.

In connection with the amended Certificate of Incorporation, holders of preferred stock were required to participate in the bridge financing on a specified pro rata basis in order to retain their preferred stock rights. Holders that participated exchanged their existing preferred stock for newly designated Series A-1, Series B-1, Series C-1, Series D-1 and Series E-1 Preferred Stock, while holders that did not participate were required to convert their preferred stock into common stock.

Following the reverse stock split, 2,892,378 shares of preferred stock were exchanged for 28,923,770 shares of Series 1 Preferred Stock and 7,943,633 shares of preferred stock were converted into common stock.

The Company accounted for the mandatory conversion of preferred stock held by Non-Participating Investors as a conversion of equity instruments rather than an extinguishment. The mandatory conversion occurred pursuant to the amended Certificate of Incorporation as part of the February 2026 recapitalization and did not result in the issuance of substantive new rights or incremental consideration. Accordingly, the carrying amount of the converted preferred stock of $66,094,943 was reclassified to common stock and additional paid-in capital. No gain or loss, deemed dividend, deemed capital contribution, or adjustment to accumulated deficit was recognized in connection with the conversion.

The exchange of preferred stock held by Participating Investors for Series A-1 through Series E-1 Preferred Stock was accounted for as a preferred stock modification. The Company concluded that the Rights Offering did not create a separately identifiable substantive freestanding right requiring separate accounting because investors did not have a meaningful economic choice between participation and non-participation, and the substantive economic rights of the Series 1 Preferred Stock remained substantially equivalent to those of the Prior Preferred Stock. Accordingly, no separate asset, equity instrument, deemed dividend, deemed capital contribution, or other transfer-of-value accounting was recognized in connection with the Rights Offering or the exchange of historical preferred stock for Series 1 Preferred Stock.

Prior to the February 2026 recapitalization, the Company's outstanding preferred stock consisted of Series A through Series E Preferred Stock, which remained outstanding as of December 31, 2025. In connection with the February 2026 recapitalization, participating holders exchanged those shares for Series A-1 through Series E-1 Preferred Stock, which remained outstanding as of March 31, 2026. The issuance of Series A-1 through Series E-1 Preferred Stock occurred solely through the exchange of existing preferred stock and did not result in the receipt of additional cash proceeds or the incurrence of additional issuance costs. Accordingly, the proceeds and issuance cost information presented below relates solely to the historical Series A through Series E Preferred Stock.

The following tables summarize (i) the Convertible Preferred Stock outstanding as of March 31, 2026 and (ii) the historical Convertible Preferred Stock outstanding as of December 31, 2025, each reflecting the 1-for-10 reverse stock split effected in February 2026.

As of March 31, 2026:

Class	Year of Issuance	Liquidation Price per Share	Shares Authorized	Shares Issued and Outstanding	Total Aggregate Liquidation Value
Series A-1	2026 (Exchange)	$ 0.40	25,250,000	—	$ —
Series B-1	2026 (Exchange)	0.80	12,500,000	—	—
Series C-1	2026 (Exchange)	1.33	35,294,203	8,030,790	10,680,951
Series D-1	2026 (Exchange)	1.33	14,143,524	5,714,250	7,599,952
Series E-1	2026 (Exchange)	1.34	21,172,590	15,178,730	20,339,498
			108,360,317	28,923,770	$ 38,620,400

Series A-1 and Series B-1 Preferred Stock were authorized as part of the February 2026 recapitalization, however, no shares of those series were outstanding as of March 31, 2026 as holders of the historical Series A and Series B Preferred Shares and certain holders of the Series C, Series D and Series E Preferred Shares did not participate in the bridge financing and where therefore converted to common stock.

As of December 31, 2025:

Class	Year of Issuance	Issuance Price per Share	Shares Authorized	Shares Issued and Outstanding	Total Proceeds or Exchange Value	Issuance Costs	Net Proceeds	Liquidation Price per Share
Series A	2013	$ 0.40	2,525,000	2,525,000	$ 1,010,000	$ —	$ 1,010,000	$ 0.40
Series B	2015	8.00	1,250,000	1,250,000	10,000,000	—	10,000,000	8.00
Series C	2015 - 2016	13.30	3,529,420	3,529,413	46,941,193	247,480	46,693,713	13.30
Series D	2018 and 2020	13.30	2,037,245	1,414,345	18,810,789	278,573	18,532,216	13.30
Series **E**	2021	13.40	4,241,659	2,117,253	28,371,190	216,950	28,154,240	13.40
			13,583,324	10,836,011	$105,133,172	$743,003	$104,390,169	

The powers, preferences, rights, qualifications, limitations, and restrictions of the shares of Convertible Preferred Stock are as follows. Unless otherwise noted, the following discussion summarizes the rights and preferences of the Series A-1 through Series E-1 Preferred Stock outstanding as of March 31, 2026.

Dividends

Dividends shall accrue to holders of the Convertible Preferred Stock at the rate of 8% of the original issue price for the applicable series of Convertible Preferred Stock per annum subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization, reclassification and other similar events payable only when, and if, declared by the Board. The right to receive dividends on Convertible Preferred Stock are not cumulative, and therefore, if not declared in any year, the right to such dividends shall terminate and shall not carryforward into the next year. There have been no dividends declared to date.

Liquidation Rights

In the event of any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary or a deemed liquidation event (which includes a merger, the sale of all of the Company's assets, or a change of control) the holders of the Convertible Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to stockholders, pari passu, at a liquidation price per share equal to the greater of: (1) the initial liquidation price of such Convertible Preferred Stock, plus any declared and unpaid dividends or (2) an amount that would have been payable had all the shares of the Convertible Preferred Stock been converted into the common stock. These payments will be made to or set aside prior to the holders of shares of any other class or series of capital stock that is not, by its terms, senior to the Convertible Preferred Stock.

Voting Rights

Holders of the applicable series of Convertible Preferred Stock are entitled to vote together with the holders of common stock as a single class on all matters submitted to a vote of the Company's stockholders, except where separate class voting is required by applicable law or the Company's Amended Certificate of Incorporation. Each share of Convertible Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which such share is then convertible.

Conversion

Each share of the applicable series of Convertible Preferred Stock is convertible, at the option of the holder, into shares of the Company's common stock in accordance with the terms of the Company's Amended and Restated Certificate of Incorporation, subject to customary anti-dilution adjustments for stock splits, stock dividends, recapitalizations, reclassifications and similar events.

The Convertible Preferred Stock will automatically convert into common stock upon the occurrence of specified automatic conversion events set forth in the Company's Amended and Restated Certificate of Incorporation, including the approval of the requisite holders of the Convertible Preferred Stock or the consummation of a qualifying public offering, as applicable.

7. EQUITY INCENTIVE PLAN

The Company's 2013 Employee, Director, and Consultant Equity Incentive Plan as amended on October 20, 2020 (the "Plan") was originally adopted by its Board and stockholders in April 2013. As of March 31, 2026 and 2025, a total of 10,640,440 and 4,150,000 shares, respectively, were reserved for issuance under the Plan. As of March 31, 2026 and 2025, zero and 208,333 common shares, respectively, remain available for issuance under the Plan.

On February 9, 2026, the Company created the 2026 Stock Incentive Plan (the "2026 Plan") which was adopted by its Board and stockholders. As of March 31, 2026, a total of 6,832,554 shares, were reserved for issuance and 1,827,050 common shares remain available for issuance under the 2026 Plan.

Stock Option Activity—Each stock option grant carries varying vesting schedules, which are generally four years. Each stock option shall terminate not more than 10 years from the date of the grant.

A summary of the stock option activity is presented in the table below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2025	3,348,729	$ 4.45	7.8	$ 907,571
Granted	275,000	2.90		
Exercised	—	—		
Forfeited	(38,890)	2.90		
Expired	(40,922)	4.16		
Outstanding at March 31, 2025	3,543,917	$ 4.35	7.8	1,116,172
Options exercisable at March 31, 2025	3,252,501	$ 4.47	7.7	867,650
Vested and expected to vest at March 31, 2025	3,543,917	$ 4.35	7.8	1,116,172
Outstanding at January 1, 2026	3,431,549	$ 4.32	6.3	$1,111,572
Granted	7,880,057	0.06		
Exercised	—	—		
Forfeited	(197,007)	2.90		
Expired	(2,692,508)	4.56		
Outstanding at March 31, 2026	8,422,091	$ 0.29	8.4	$ 236,402
Options exercisable at March 31, 2026	7,624,614	$ 0.31	8.2	$ 212,563
Vested and expected to vest at March 31, 2026	8,422,091	$ 0.29	7.8	$ 236,402

The weighted-average grant date fair value of stock options granted during the three months ended March 31, 2026 and 2025, were $0.06 and $2.78, respectively. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those stock options that had an exercise price lower than the fair value of the Company’s common stock.

The Company utilized the Black-Scholes option-pricing model for determining the estimated fair value of options. The Black-Scholes option-pricing model requires the use of subjective assumptions. The assumptions used to value stock option grants for the three months ended March 31, 2026, were as follows:

	March 31, 2026
Fair value of common stock	$0.09
Risk-free interest rate	3.80% - 3.90%
Expected dividend yield	—
Weighted-average expected term	5.1 years
Expected volatility	75%

Risk-Free Interest Rate—The risk-free interest rate for periods within the expected term of the awards is based on the US Treasury yield curve in effect at the time of the grant.

Expected Dividend Yield—The Company has never declared or paid any cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Expected Term—The Company calculates the expected term using the "simplified" method, which is the simple average of the vesting period and the contractual term. The simplified method is applied as the Company does not have sufficient historical data to provide a reasonable basis for an estimate of the expected term.

Expected Volatility—As the Company has been privately held since inception, there is no specific historical or implied volatility information available. Accordingly, the Company estimates the expected volatility on the historical stock volatility of a group of similar companies that are publicly traded over a period equivalent to the expected term of the stock option awards.

Exercise Price—The exercise price is taken directly from the grant notice issued to employees and nonemployees.

The Company's stock-based compensation expense is allocated to the following operating expense categories on the statements of operations and comprehensive loss for the quarters ended March 31, 2026 and 2025, as follows:

	March 31, 2026	March 31, 2025
Research and development	$225,891	$ 27,220
General and administrative	253,525	15,201
Total stock-based compensation expense	$479,416	$ 42,421

No related tax benefits of the stock-based compensation expense have been recognized, and no related tax benefits have been realized from the exercise of stock options due to the Company's net operating loss carryforwards.

Total unrecognized stock-based compensation expense as of March 31, 2026 and 2025, was $587,402 and $763,411, respectively, which will be recognized over the remaining weighted-average vesting period of 3.07 years and 3.62 years, respectively.

8. INCOME TAXES

There were no income taxes recorded for the three months ended March 31, 2026 or March 31, 2025 and, therefore, the Company's effective income tax rate was 0.0% for the three months ended March 31, 2026 and March 31, 2025. The effective income tax rate for the three months ended March 31, 2026 and 2025 differed from the 21% federal statutory rate primarily due to the valuation allowance maintained against the Company's net deferred tax assets.

9. COMMITMENTS AND CONTINGENCIES

Commitments

The Company sponsors a 401(k) defined contribution plan covering all eligible US employees. Contributions to the 401(k) plan are discretionary. The Company did not make any matching contributions to the 401(k) plan for the quarters ended March 31, 2026 and 2025.

Contingencies

The Company does not have any outstanding or ongoing litigation and legal matters.

10. SUBSEQUENT EVENTS

In connection with the preparation of the financial statements, the Company evaluated events subsequent to the balance sheet date of March 31, 2026 through July 29, 2026, the date the financial statements were available for issuance.

In April 2026, the Company issued an additional $10,000,000 of senior secured convertible promissory notes. The additional notes were issued on substantially the same terms as the notes issued in February 2026.

In May 2026, the Company amended the existing 2026 Plan to increase the shares of common stock reserved for issuance from 6,832,554 shares to 35,000,000 shares.

The Board of Directors authorized the grant of options to purchase a total of 29,553,780 shares of common stock to management, employees and select consultants and advisors at a weighted average exercise price of $0.58 per share on May 12, 2026.

Merger Agreement

On May 17, 2026, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Quince Therapeutics, Inc. ("Quince"), Phoenix Merger Sub I, Inc., Phoenix Merger Sub II, LLC and Orphai Holdings Therapeutics, Inc., pursuant to which the Company was acquired by Quince. Under the terms of the Merger Agreement, Merger Sub I merged with and into Orphai Holdings Therapeutics, Inc., with Orphai Holdings Therapeutics, Inc. surviving as a wholly owned subsidiary of Quince, followed immediately by the merger of Orphai Holdings Therapeutics, Inc. with and into Merger Sub II, pursuant to which Merger Sub II was the surviving entity.

Pursuant to the Merger Agreement, holders of Orphai equity securities received an aggregate of 3,258,517 shares of Quince common stock and 67,101.2355 shares of Quince Series C Non-Voting Convertible Preferred Stock, subject to the terms and conditions set forth in the Merger Agreement. Outstanding Company options and warrants were assumed or exchanged for corresponding Quince equity instruments, and the Company's outstanding convertible notes converted into equity immediately prior to the effective time of the merger in accordance with their terms.

In connection with the execution of the Merger Agreement, Quince entered into securities purchase agreements with certain investors providing for a private placement financing which generated gross proceeds of $115,000,000 through the issuance of Quince Series C Convertible Preferred Stock and related warrants, subject to the satisfaction of customary closing conditions.

* * * * * *

Exhibit 99.8

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED FINANCIAL INFORMATION

On May 18, 2026, Quince Therapeutics, Inc., a Delaware corporation (the "Company" or "Quince"), acquired Orphai Therapeutics, LLC (formerly Orphai Therapeutics, Inc., "Orphai"), a Delaware limited liability company and wholly owned subsidiary of Orphai Holdings Therapeutics, Inc., a Delaware corporation ("HoldCo"), in accordance with the terms of the 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 ("First Merger Sub"), Phoenix Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Second Merger Sub"), Orphai, and HoldCo. Pursuant to the Merger Agreement, First Merger Sub merged with and into HoldCo, pursuant to which HoldCo was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately following the First Merger, HoldCo merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (together with the First Merger, the "Acquisition"). All of the assets acquired by Quince consisted of the assets of Orphai Therapeutics, LLC (formerly Orphai Therapeutics, Inc.). None of the assets acquired were attributable to HoldCo, the parent entity of Orphai. HoldCo was incorporated solely as a holding company to facilitate the structure of the Acquisition, had no independent operations or assets and held all operating assets through Orphai; accordingly, the historical financial statements of Orphai are presented as the predecessor financial statements for purposes of this pro forma.

Under the terms of the Merger Agreement, following the closing of the Acquisition, the Company issued consideration (i) to the stockholders of HoldCo an aggregate of 162,971 shares of common stock of the Company, par value $0.001 per share (the "Common Stock"), as adjusted for the second reverse stock split and 67,101.235 shares of Series C Non-Voting Convertible Preferred Stock, par value $0.001 per share (the "Series C Preferred Stock"), each share of which is convertible into 52.00 shares of Common Stock, as adjusted for the June 29, 2026 reverse stock split, subject to certain conditions, including the approval of such conversion by the Company's stockholders, (ii) 10,964.505 warrant shares of the Company's Series C Preferred Stock to Orphai warrant holders. The warrants may be exercised for a fixed number of shares of the Company's Series C Preferred Stock equal to 50% of the principal amount of each warrant divided by the upfront per share price of the Company's Preferred stock, multiplied by 1.25. The warrants will become exercisable for Common Stock following approval of the Company Stockholder Matters (as defined below), subject to certain beneficial ownership limitations, and (iii) historical Orphai's options outstanding and unexercised, whether or not vested, were assumed and converted into and became an option to purchase the Company's Common Stock (1,887,322 as adjusted for the June 29, 2026 reverse stock split). The number of shares of the Company's Common Stock subject to each option shall be determined by multiplying the number of shares of the Orphai's Common Stock subject to the option prior to the transaction by the Exchange Ratio, defined as 0.6935, and rounding down to the nearest whole share. The per share exercise price shall be determined by dividing the per share exercise price of the Orphai's Common Stock in effect prior to the Transaction by the Exchange Ratio.

Immediately prior to and in connection with the Acquisition, the historical equity structure of Orphai was modified as follows: (a) stockholders of Orphai preferred stock were issued Common Stock or Series C Preferred Stock of the Company, (b) all the outstanding and unexercised warrants of Orphai were cancelled and replaced with a warrant to purchase shares of the Series C Preferred Stock of the Company, and (c) all outstanding convertible notes outstanding were converted into shares of the Company's Common Stock

On May 18, 2026, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement", "Private Placement", or "Financing") with the purchasers named therein. Under the Purchase Agreement, which was a closing condition of the Merger Agreement, the Company agreed to sell an aggregate of (i) 144,200.633 shares of Series C Preferred Stock and (ii) warrants (the "Financing Warrants") to purchase 72,100.322 shares of Series C Preferred Stock for an aggregate cash purchase price of approximately $115 million (collectively, the "Financing"). Each share of Series C Preferred Stock is convertible into 52.00 shares of Common Stock, as adjusted for the June 29, 2026 reverse stock split, subject to certain conditions, including the approval of such conversion by the Company's stockholders. 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 Trial and (b) the termination or suspension of the LAM-001 Trial and through the 30th day following such public announcement and will exercisable at a price equal to $996.90 per share of Series C Preferred Stock (or $0.9969 per share on an as-converted-to-common basis) for up to an additional approximately $72 million in additional proceeds if exercised in full. The Financing Warrants will become exercisable for Common Stock following approval of the Company Stockholder Matters (as defined below), subject to certain beneficial ownership limitations.

Under the Merger Agreement and the Purchase Agreement the Company has agreed to hold a stockholders' meeting to submit the following matters to its stockholders for their consideration (i) the approval, in accordance with the rules of the Nasdaq Stock Market, LLC ("Nasdaq") of the conversion of the Series C Preferred Stock into shares of Common Stock, (ii) the approval of the transactions contemplated by the Merger Agreement and the Financing in accordance with applicable Nasdaq listing rules (the "Nasdaq Proposals"), (iii) the amendment of the Company's amended and restated certificate of incorporation to authorize an increase to the number of authorized shares of the Company's Common Stock from 250,000,000 up to 800,000,000 shares of Common Stock (the "Charter Amendment Proposal" and, together with the Conversion Proposal and the Nasdaq Proposals, the "Company Stockholder Matters"), (iv) (a) the approval of the Company's 2026 Equity Incentive Plan, which will provide for new awards for a number of shares of Common Stock not exceeding 15% of the fully diluted shares of capital stock of the Company outstanding immediately after the Financing, and subject to approval by the board of directors of the Company (the "Board"), and which will include an "evergreen" provision providing for an annual increase of up to 5% of the total number of fully diluted shares of capital stock of the Company outstanding as of the day prior to such increase and (b) the approval of the 2026 Employee Stock Purchase Plan with a total pool of shares of Common Stock not exceeding 1% of the fully diluted shares of capital stock of the Company outstanding immediately after the closing of the Financing, and which will include an "evergreen" provision providing for an annual increase of up to 1% of the total number of fully diluted shares of capital stock of the Company outstanding as of the day prior to such increase, and (v) such other changes or approvals as may be mutually agreed by the Company and Orphai. In connection with these matters, the Company intends to file with the Securities and Exchange Commission (the "SEC") a proxy statement and other relevant materials.

The unaudited pro forma condensed combined consolidated financial information should be read in conjunction with:

- Quince's audited consolidated financial statements, and related notes thereto, for the year ended December 31, 2025, included in Quince's Annual Report on Form 10-K for the year ended December 31, 2025;
- Quince's unaudited condensed consolidated financial statements and accompanying notes as of and for the three months ended March 31, 2026, included in Quince's Quarterly Report on Form 10-Q for the period ended March 31, 2026;
- Orphai's audited financial statements as of and for the year ended December 31, 2025, included as Exhibit 99.1 to this Form 8-K/A;
- Orphai's unaudited financial statements as of and for the three months ended March 31, 2026 and 2025, included as Exhibit 99.2 to this Form 8-K/A; and
- The accompanying notes to the unaudited pro forma condensed combined consolidated financial information.

The unaudited pro forma condensed combined consolidated financial information has been prepared by management in accordance with Article 11, Pro Forma Financial Information, under Regulation S-X, and is for illustrative and informational purposes only. The unaudited pro forma condensed combined consolidated financial is not necessarily indicative of what the combined company's financial position or results of operations actually would have been had the acquisition been consummated as of the dates indicated. In addition, the unaudited pro forma condensed combined consolidated financial information do not purport to project the future financial position or operating results of the combined company.

The historical financial statements of the Company and Orphai have been adjusted in the accompanying unaudited pro forma condensed combined consolidated financial information give effect to pro forma events which are necessary to account for the Acquisition and the Private Placement, in accordance with accounting principles generally accepted in the United States ("GAAP"). The unaudited pro forma adjustments are based upon available information and certain assumptions that management believes are reasonable under the circumstances.

For accounting purposes, the Company is considered to be the acquiring company and the transaction is accounted for as an asset acquisition as Orphai did not meet the definition of a business under Accounting Standard Codification Topic 805, *Business Combinations* ("ASC 805") as substantially all of its value was in the In Process Research & Development ("IPR&D") asset. Accordingly, the assets and liabilities of the Company will be recorded as of the Acquisition closing date at their respective carrying values, and the acquired net assets and assumed liabilities of Orphai will be recorded as of the Acquisition closing date at their fair value. The Company was determined to be the accounting acquirer based upon the terms of the Acquisition.

As a result of the foregoing, the unaudited pro forma condensed combined consolidated financial information is based on the preliminary information available and management's preliminary valuation of the fair value of tangible and intangible assets acquired and liabilities assumed. The actual purchase accounting assessment may vary based on final analyses of the valuation of assets to be acquired and liabilities to be assumed, particularly in regard to indefinite and definite-lived intangible assets and deferred tax assets and liabilities, which could be material.

The Company effected an initial reverse stock split of our outstanding common stock and Exchangeable Shares at a ratio of 1-for-10, effective as of 11:59 p.m., Eastern Time, on April 10, 2026. The Company has reflected the reverse stock split herein, unless otherwise indicated. However, the information set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 has not been adjusted to give effect to such reverse stock split.

The Company effected a second reverse stock split of our outstanding common stock and exchangeable Shares at a ratio of 1-for-20, effective as of 11:59 p.m., Eastern Time, on June 29, 2026. The Company has reflected the reverse stock split herein, unless otherwise indicated. However, the information set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 and the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2026 has not been adjusted to give effect to such reverse stock split.

QUINCE THERAPEUTICS, INC., AND SUBSIDIARIES
UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED BALANCE SHEET
AS OF MARCH 31, 2026
(in thousands)

	Quince	Orphai (a)	Private Placement Adjustments (b)	Acquisition Pro Forma Adjustments		Pro Forma Combined Company
ASSETS						
Current assets:						
Cash and cash equivalents	$ 18,163	$ 431	$ 115,000	$ (4,298)	**(c)**	$ 129,296
Prepaid expenses and other current assets	7,417	266	—	—		7,683
Total current assets	25,580	697	115,000	(4,298)		136,979
Property and equipment, net	550	—	—	—		550
Operating lease right-of-use assets, net	415	—	—	—		415
Other assets	78	—	—	—		78
Total assets	$ 26,623	$ 697	$ 115,000	$ (4,298)		$ 138,022
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts payable	$ 5,392	$ 1,726	$ —	$ —		$ 7,118
Accrued expenses and other current liabilities	3,376	620	11,361	2,139	**(d)**	17,496
Total current liabilities	8,768	2,346	11,361	2,139		24,614
Long-term operating lease liabilities	293	—	—	—		293
Convertible notes	—	10,447	—	(10,447)	**(e)**	—
Warrant liabilities	694	3,012	11,536	58(f)		15,300
Other non-current liabilities	1,196	—	—	—		1,196
Total liabilities	10,951	15,805	22,897	(8,250)		41,403
Mezzanine equity:						
Preferred stock - Series C	—	—	93,243	48,146	**(g)**	141,389
Redeemable convertible preferred stock	—	35,912	—	(35,912)	**(h)**	—
Stockholders' equity:						
Preferred stock	—	—	—	—		—
Common stock	14	478	—	(475)	**(h)**	17
Additional paid in capital	435,587	78,463	—	(71,881)	**(h)**	442,169
Accumulated other comprehensive loss	4,610	—	—	—		4,610
Accumulated deficit	(424,539)	(129,961)	(1,140)	64,074	**(h)**	(491,566)
Total stockholders' equity	15,672	(51,020)	(1,140)	(8,282)		(44,770)
Total liabilities, mezzanine equity and stockholders' equity	$ 26,623	$ 697	$ 115,000	$ (4,298)		$ 138,022

QUINCE THERAPEUTICS, INC., AND SUBSIDIARIES
UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2026
(In thousands, except share and per share amounts)

	Quince	Orphai (a)	Private Placement Adjustments (b)	Acquisition Pro Forma Adjustments		Pro Forma Combined Company	
Operating expenses:							
Research and development	$ 6,845	$ 1,410	$ —	$ —		$ 8,255	
General and administrative	4,267	1,009	—	—		5,276	
Intangible asset impairment charge	67,808	—	—	—		67,808	
Fair value adjustment for contingent consideration	(64,330)	—	—	—		(64,330)	
Total operating expenses	14,590	2,419	—	—		17,009	
Loss from operations	(14,590)	(2,419)	—	—		(17,009)	
Fair value adjustment for debt	12,168	—	—	—		12,168	
Fair value adjustment of notes	—	(946)	—	946	**(f)**	—	
Fair value adjustment of warrants	31,116	397	—	(397)	**(f)**	31,116	
Interest income	160	3	—	—		163	
Other income (expense), net	1,719	16	—	—		1,735	
Net loss before income tax benefit	30,573	(2,949)	—	549		28,173	
Income tax benefit (loss)	5,339	—	—	—		5,339	
Net income (loss)	35,912	(2,949)	—	549		33,512	
Other comprehensive loss:							
Foreign currency translation adjustments	(1,135)	—	—	—		(1,135)	
Unrealized loss on available-for-sale securities	(5)	—	—	—		(5)	
Total comprehensive income (loss)	$ 34,772	$(2,949)	$ —	$ 549		$ 32,372	
Net income (loss) per share – basic (1)	$ 71.91					$ 2.88	**(h)**
Weighted average shares of common stock outstanding – basic (1)	456,014			11,150,699	**(g)**	11,606,713	**(h)**
Net income (loss) per share – diluted (1)	$ 57.58					$ 2.33	**(h)**
Weighted average shares of common stock outstanding – diluted (1)	459,520			11,150,699	**(g)**	11,610,219	**(h)**

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

QUINCE THERAPEUTICS, INC., AND SUBSIDIARIES
UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2025
(in thousands, except share and per share amounts)

	Quince	Orphai (a)	Private Placement Adjustments (b)	Acquisition Pro Forma Adjustments		Pro Forma Combined Company	
Operating expenses:							
Research and development	$ 35,382	$ 4,004	$ —	$ 59,000	(c)	$ 98,386	
General and administrative	15,047	2,162	—	6,437	(d)	23,646	
Goodwill impairment charge	—	—	—	—		—	
Fair value adjustment for contingent consideration	7,639	—	—	—		7,639	
Loss on acquisition	—	—	—	450	(e)	450	
Total operating expenses	58,068	6,166	—	65,887		130,121	
Loss from operations	(58,068)	(6,166)	—	(65,887)		(130,121)	
Fair value adjustment for debt	(2,043)	—	—	—		(2,043)	
Fair value adjustment of notes	—	(1,413)	—	1,413	(f)	—	
Fair value adjustment of warrants	(21,470)	(2,239)	—	2,239	(f)	(21,470)	
Loss of exchange of convertible notes	—	(1,502)	—	1,502	(f)	—	
Warrant issuance costs	(914)	—	(1,140)	—		(2,054)	
Interest income	1,244	32	—	—		1,276	
Other income (expense), net	486	(4)	—			482	
Net loss before income tax expense	(80,765)	(11,292)	(1,140)	(60,733)		(153,930)	
Income tax expense	(3,214)	—	—	—		(3,214)	
Net loss	(83,979)	(11,292)	(1,140)	(60,733)		(157,144)	
Other comprehensive loss:							
Foreign currency translation adjustments	5,849	—	—	—		5,849	
Unrealized gain (loss) on available-for-sale securities	(64)	—	—	—		(64)	
Total comprehensive loss	$ (78,194)	$(11,292)	$ (1,140)	$ (60,733)		$ (151,359)	
Net loss per share - basic and diluted (1)	$ (335.27)					$ (13.78)	(h)
Weighted average shares of common stock outstanding - basic and diluted (1)	250,484			11,150,699	(g)	11,401,183	(h)

(1) Adjusted prior period net income (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 1-for-20 reverse stock split effected on June 29, 2026.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED FINANCIAL INFORMATION

Note 1. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined consolidated financial information and related notes are prepared in accordance with Article 11 of Regulation S-X, Pro Forma Financial Information, as amended by the final rule, Amendments to Financial Disclosures About Acquired and Disposed Businesses, as adopted by the SEC on May 20, 2020.

The accounting policies used in the preparation of the unaudited pro forma consolidated and combined financial information are those set forth in the Company's audited consolidated financial statements for the year ended December 31, 2025. Management conducted a comprehensive review of the accounting policies of both the Company and Orphai to identify potential policy differences. Based on information available and management's current understanding, no significant accounting policy differences have been identified that would require adjustments to the unaudited pro forma consolidated and combined financial information. Both the Company's and Orphai's historical financial statements were prepared in accordance with GAAP and presented in U.S. dollars.

The unaudited pro forma condensed combined consolidated financial information was prepared under the assumption that the Company is the accounting acquirer. The Company identified Orphai as a variable interest entity ("VIE") under Accounting Standard Codification Topic 810, *Consolidations* (ASC 810), where the Company is the primary beneficiary. The transaction is accounted for as an asset acquisition as Orphai did not meet the definition of a business under Accounting Standard Codification Topic 805, *Business Combinations* ("ASC 805") as substantially all of its value was in the In Process Research & Development asset. Accordingly, the assets and liabilities of the Company will be recorded as of the Acquisition closing date at their respective carrying values, and the acquired net assets and assumed net liabilities of Orphai will be recorded as of the Acquisition closing date at their fair value. The Company was determined to be the accounting acquirer based upon the terms of the Acquisition.

The unaudited pro forma condensed combined consolidated balance sheet as of March 31, 2026 combines the historical consolidated balance sheets of Quince and Orphai as of such date, giving effect to adjustments depicting the accounting for the Acquisition and Private Placement. The unaudited pro forma condensed combined consolidated statements of operations for the three months ended March 31, 2026 and the year ended December 31, 2025, combines the historical consolidated statements of operations of Quince and Orphai, giving effect to adjustments made on the unaudited pro forma condensed combined consolidated balance sheet depicting the accounting for the Acquisition and Private Placement assuming the Acquisition and Private Placement were consummated on January 1, 2025.

The unaudited pro forma condensed combined consolidated financial information and related notes are provided for illustrative purposes only and do not purport to represent what the combined company's actual results of operations or financial position would have been had the Acquisition been completed on the dates indicated, nor are they necessarily indicative of the combined company's future results of operations or financial position for any future period. The actual financial position and results of operations may differ significantly from the pro forma amounts reflected herein.

The unaudited pro forma condensed combined consolidated financial information also do not reflect any cost savings or operating synergies that the combined company may achieve as a result of the Acquisition, the total expected costs to integrate the operations of Quince and Orphai, or the total expected costs necessary to achieve such cost savings and operating synergies. Although the Company believes that certain cost savings may result from the Acquisition, there can be no assurance that these cost savings will be achieved.

Note 2. Estimate of Consideration Transferred and Preliminary Allocation of Consideration Transferred

The transaction was accounted for under asset acquisition accounting in accordance with ASC 805, and as such, assets acquired and liabilities assumed were recorded at their estimated fair values on the acquisition date. Under ASC 810, the Company had identified Orphai as a VIE but did not meet the definition of a business, no goodwill is recognized and in accordance with ASC 805, a loss (or gain) is recognized for the difference between the consideration transferred and the fair value of the net assets acquired. The fair value of the assets and liabilities in the unaudited pro forma condensed combined consolidated financial information are based upon a preliminary assessment of fair value and may change as the valuation for the intangible asset is finalized.

The fair value of the preliminary estimated consideration transferred totaled $58.6 million, summarized as follows (in thousands):

	Fair Value of Consideration
Common stock consideration (a)	$ 3,242
Preferred stock consideration (b)	48,146
Warrant consideration (c)	3,070
Assumed share-based awards (d)	4,161
Fair value of total consideration transferred	$ 58,619

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

(b) The preliminary estimated 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 Private Placement transaction.

(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.

(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 equal to the product of (i) the number of shares of Orphai Common Stock subject to the award (1,887,322) multiplied by (ii) the equity award Exchange Ratio of 0.6935.

The calculation of consideration transferred includes the portion of fair-value-based measure of the acquiree award that relates to the pre-combination service period in consideration transferred. 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.

For purposes of this pro forma analysis, the above estimated consideration transferred has been allocated based on a preliminary estimate of the fair value of assets and liabilities to be acquired, with the excess recorded to loss on acquisition (in thousands).

Preliminary estimate of the assets acquired and liabilities assumed	**Estimated Fair Value**
Assets acquired:	
Cash and cash equivalents	$ 8,001
Prepaid expenses and other current expenses	451
In-process research and development ("IPR&D") (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
Loss on acquisition (f)	$ 450

(e) IPR&D represents the research and development projects of Orphai which were in-process, but not yet completed, and which Quince plans to advance. Current accounting standards (ASC 730) require that the fair value of IPR&D projects acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expenses at the acquisition date. The final valuation of the IPR&D consideration could differ significantly from the current estimate.

(f) The loss on acquisition represents the difference between the acquisition date fair value of the consideration transferred and the measurement of the assets acquired, and liabilities assumed applying ASC 805 Business Combinations.

The preliminary allocation of consideration transferred above, which is as of the acquisition date of May 18, 2026 has been used to prepare the pro forma adjustments in the unaudited pro forma condensed combined consolidated balance sheet and unaudited pro forma condensed combined consolidated statement of operations.

The fair values of assets acquired and liabilities assumed are based on preliminary estimates of fair values as of the acquisition date. Management believes the fair values recognized for the assets acquired and liabilities assumed are based on reasonable estimates and assumptions. Preliminary fair value estimates may change as additional information becomes available. There can be no assurance that the final determination will not result in material changes from these preliminary amounts.

Note 3. Pro Forma Adjustments

The pro forma adjustments are based on the Company's preliminary estimates and assumptions that are subject to change. The following adjustments have been reflected in the unaudited pro forma condensed combined consolidated financial information:

Unaudited Pro Forma Condensed Combined Consolidated Balance Sheet as of March 31, 2026

(a) Reflects the unaudited consolidated balance sheet for Orphai as of March 31, 2026.

(b) Reflects the Private Placement that was a closing condition of the merger and reflects (1) the gross proceeds raised of $115,000 thousand received from the Private Placement transaction, (2) the direct transaction costs incurred of $11,361 thousand; (3) the issuance of Financing Warrants recorded at the fair value of the Financing Warrant liability; (4) the issuance of 144,200.633 new Series C Preferred Stock, net of allocated transaction fees of $93,243 thousand; and (5) the allocated Financing Warrant issuance costs of $1,140 thousand.

(c) Reflects an adjustment to cash on hand that is payable upon consummation of the acquisition $4,298 thousand representing the Orphai's expense paid by Quince, on behalf of Orphai to a third party and reflected in Orphai's opening balance sheet.

(d) Represents the adjustments related to acquisition-related cost incurred, reflected in increased Accrued expenses and other current liabilities of $2,139 thousand, which includes the accrual of acquisition-related costs of $6,437 and the payment of Orphai's expenses of $4,298 described in (c).

(e) Represents the adjustments of $10,447 thousand to Orphai's convertible notes, which were not assumed by Quince as they were converted to Series C Preferred Stock and warrants.

(f) Represents the adjustment to record the estimated fair value of the warrant liability of $3,070 thousand, offset by the adjustment to the historical Orphai warrant liability of $3,012 thousand, which were converted to Quince issued warrants as part of Acquisition.

(g) Represents the adjustment to record the estimated fair value of the issuance of the 67,101.235 Series C Preferred Stock issued, with a par value of $0.001, of $48,146 thousand.

(h) Reflects adjustments to eliminate Orphai's historical equity balances, adjustments related to the acquisition, and to record estimated consideration of equity consideration (in thousands).

Elimination of Orphai historical preferred stock	$ (35,912)
Pro forma adjustment to preferred stock	$ (35,912)
Elimination of Orphai historical common stock	$ (478)
Common stock issued as part of equity consideration of the acquisition	3
Pro forma adjustment to common stock	$ (475)
Elimination of Orphai historical paid-in capital in excess of par value	$ (78,463)
To reflect the fair value of the common stock issued in excess of par value	3,239
Fair value of assumed share-based awards as part of acquisition	4,161
Net acquired assets and assumed liabilities	(818)
Pro forma adjustment to paid-in capital in excess of par value	$ (71,881)
Elimination of Orphai accumulated deficit	$129,961
Estimated transaction costs	(6,437)
In-process research and development	(59,000)
Loss on acquisition	(450)
Pro forma adjustment to accumulated deficit	$ 64,074

Unaudited Pro Forma Condensed Combined Consolidated Statement of Operations and Comprehensive Loss for the Three Months Ended March 31, 2026 and the Year Ended December 31, 205

(a) Reflects the audited consolidated statement of operations and comprehensive loss for Orphai for the year ended December 31, 2025 and the unaudited consolidated statement of operations and comprehensive loss for Orphai for the three months ended March 31, 2026.

(b) Reflects the Private Placement and the transaction costs allocated to the issuance of Financing Warrants of $1,140 thousand.

(c) Reflects the expense of the fair value of IPR&D project acquired in an asset acquisition with no alternative future use of $59,000 thousand.

(d) Reflects the acquisition-related costs incurred by Quince subsequent to March 31, 2026 and are reflected in (1) accumulated deficit and accrued expenses in the unaudited pro forma condensed combined consolidated balance sheet and (2) general and administrative expenses in the unaudited pro forma condensed combined consolidated statements of operations and comprehensive income for the year ended December 31, 2025.

(e) Reflects adjustments due to loss on acquisition as a result of the difference between the consideration transferred and the fair value of the assets acquired and liabilities assumed.

(f) Reflects the adjustment of $5,154 thousand for the year ended December 31, 2025, for the change in fair value of Orphai notes ($1,413 thousand), change in fair value of Orphai warrants ($2,239 thousand), and loss of exchange of convertible notes ($1,502 thousand), as they were converted to Quince's warrants and Series C Preferred Stock.

Reflects the adjustment of $549 thousand for the three months ended March 31, 2026, for the change in fair value of Orphai notes ($946 thousand), offset by the change in fair value of Orphai warrants for Orphai ($397 thousand), as they were converted to Quince's warrants and Series C Preferred Stock.

(g) Reflects the adjustments to the weighted average shares outstanding for the Acquisition and Private Placement.

	Three Months Ended March 31, 2026		Year Ended December 31, 2025	
	Basic	Diluted	Basic	Diluted
Quince weighted average shares outstanding	456,014	456,014	250,484	250,484
Quince common stock issued in Acquisition	162,971	162,971	162,971	162,971
Quince preferred stock issued in Acquisition (i) (ii)	3,489,281	3,489,281	3,489,281	3,489,281
Quince preferred stock issued in Private Placement (i) (ii)	7,498,447	7,498,447	7,498,447	7,498,447
Pre-funded warrants from Quince	—	3,140	—	—
Outstanding options from Quince	—	366	—	—
Pro Forma combined shares outstanding	11,606,713	11,610,219	11,401,183	11,401,183

(i) Presented on an as-converted basis to Common Stock

(ii) The Company's Series C Preferred Stock is contractually structured to participate in the economic risks and rewards of common stock on an identical, one-for-one basis and possesses mandatory conversion features. Consequently, these shares are treated as common stock equivalents for financial reporting purposes. The weighted-average number of these preferred shares has been included in the denominator of the basic and diluted earnings per share calculation and no preferred dividend deduction is made from net income in the numerator.

(h) Basic net income (loss) per share of common stock is determined by dividing net income (loss), after considering income (loss) attributable to participating securities, by the weighted average number of common shares outstanding, including the Company's Series C Preferred Stock, during the period. The Series C Preferred Stock is contractually structured to participate in the economic risks and rewards of common stock on an identical, one-for-one basis and possesses mandatory conversion features.

Diluted net income (loss) per share of common stock includes the effect of Quince's warrants and share-based awards if the inclusion of these items is dilutive.

	March 31, 2026	December 31, 2025
Numerator:		
Net income (loss)	$ 33,512	$ (157,144)
Undistributed earnings allocated to participating securities	(125)	
Net income (loss) – basic	$ 33,387	$ (157,144)
Net income (loss)	$ 33,512	$ (157,144)
Fair value adjustment for pre-funded warrants	(6,358)	—
Undistributed earnings allocated to participating securities	(101)	—
Net income (loss) – diluted	$ 27,053	$ (157,144)
Denominator:		
Weighted average shares of common stock outstanding – basic	11,606,713	11,401,183
Effect of dilutive shares		
Pre-funded warrants from Quince	3,140	—
Outstanding options from Quince	366	—
Weighted average shares of common stock outstanding – diluted	11,610,219	11,401,183
Net income (loss) per share – basic	$ 2.88	$ (13.78)
Net income (loss) per share – diluted	$ 2.33	$ (13.78)