UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-38130

Rein Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**13-4196017**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12407 N. Mopac Expy. Suite 250 #390 Austin, TX	**78758**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (737) 802-1989

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, $0.001 par value	**RNTX**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

As of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the last reported sale price of the shares of common stock on The Nasdaq Capital Market was $32,264,569.

As of March 24, 2026 the Registrant has 28,039,032 shares of Common Stock, $0.001 par value per share, outstanding.

Portions of the Registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the end of the Registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K of Rein Therapeutics, Inc. ("Rein," "we," "us," "our," or the "Company") contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans to develop and commercialize LTI-03, including the potential benefits thereof;
- our ability to secure sufficient additional capital in the near term or implement other strategies needed to alleviate our current substantial doubt about our ability to continue as a going concern;
- our expectations regarding our ability to fund our operating expenses, our planned activities, and capital expenditure requirements with our cash, cash equivalents and investments
- our Phase 2 clinical trial of LTI-03 and our ability to re-start and complete such clinical trial, subject to obtaining additional funding;
- our decision to further delay clinical development of LTI-01 for an undetermined period of time until additional funds are raised;
- our unproven approach to drug research and development in the area of fibrotic diseases, with a focus on Caveolin-1, or Cav1, related peptides, and our ability to develop marketable products;
- our future clinical trials for LTI-03, whether conducted by us or by any future collaborators, including our ability to enroll patients in our clinical trials, the timing of initiation of these trials and of the anticipated results;
- the success of our remediation efforts related to the material weaknesses identified in our internal controls over financial reporting;
- the timing of and our ability to obtain and maintain marketing approvals for LTI-03;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy, and our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of LTI-03, LTI-01 and any additional future product candidates;
- our reliance on third-party manufacturing and supply vendors and contract research organizations, or CROs;
- potential benefits of any future collaboration;
- developments relating to our competitors and our industry;
- the impact of general economic conditions, including inflation and the imposition of new or revised tariffs or other trade restrictions; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K, or the Annual Report, and subsequently filed reports, particularly in the "Risk Factors" section, which could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report and the documents that we reference herein and have filed or incorporated by reference hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Annual Report includes or incorporates by reference statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

Effective on January 10, 2025, we amended our Restated Certificate of Incorporation, as amended, to effect a change in our name from "Aileron Therapeutics, Inc." to "Rein Therapeutics, Inc." Unless the context otherwise requires, references in this Annual Report to "we," "us," "our" and the "Company" refer to Rein Therapeutics, Inc. and its wholly owned subsidiaries.

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which you should be aware in evaluating our company and our business. These risks are discussed more fully in the "Risk Factors" section of this Annual Report. These risks include the following:

Risks Related to Our Financial Condition

- We believe that our existing cash and cash equivalents as of December 31, 2025, together with the proceeds received by us pursuant to the securities purchase agreements we entered into in January 2026 and February 2026, will be sufficient to enable us to fund our planned operating expense and capital expenditure requirements into the second quarter of 2026, as a result we will need to obtain sufficient additional funding in order to sustain our current level of operations and complete our Phase 2 RENEW clinical trial of LTI-03.
- We will require substantial additional capital to finance our operations beyond the second quarter of 2026 and to complete the development and commercialization of our product candidates. Due to our current liquidity constraints, we have paused development of LTI-01 and other preclinical programs for an undetermined period and are prioritizing LTI-03. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay our clinical and research and development program, future commercialization efforts or other operations.
- We have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.
- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

Risks Related to the Discovery, Development and Commercialization of Product Candidates

- Our business is highly dependent on the success of our product candidate, LTI-03, which is now screening and recruiting patients in a Phase 2 clinical trial that initiated in May 2025.
- Our approach to drug research and development in the area of fibrotic diseases, with a focus on Cav1-related peptides, is unproven and may not result in marketable products.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial, do not necessarily predict final results and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration, or the FDA, or comparable foreign regulatory authorities.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of LTI-03.
- Our future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies or earlier clinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.
- We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

Risks Related to Our Dependence on Third Parties

- We rely on third parties to conduct certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

Risks Related to Our Intellectual Property

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- We are currently party to license or other collaboration agreements that impose certain obligations on us, and we may enter into additional license or collaboration agreements in the future. If we fail to comply with our obligations under such present or future agreements with third parties, we could lose license rights that may be important to our business.

Risks Related to Our Common Stock

- Assuming the conversion of all outstanding Series X Non-Voting Convertible Preferred Stock, or the Series X Preferred Stock, and the exercise of outstanding warrants to purchase shares of our common stock, or the Warrants, there is a concentration of ownership of our outstanding common stock by entities and individuals affiliated with Bios Partners. If this group chooses to act together, it could exert substantial influence over our business, and the interests of this group may conflict with those of other stockholders.

PART I

Item 1. Business

Overview and Recent Developments

We are a clinical stage biopharmaceutical company focused on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. We currently have two product candidates in clinical development, LTI-03 and LTI-01, however, due to insufficient funding we have paused development of LTI-01 for an undetermined period of time and are prioritizing LTI-03. Our pipeline includes:

- LTI-03, a peptide, for which we conducted a Phase 1b dose-ranging, placebo-controlled safety, tolerability, and pharmacodynamic biomarker activity trial in development for the treatment of Idiopathic Pulmonary Fibrosis, or IPF, that has demonstrated the ability to protect healthy lung epithelial cells and reduce pro-fibrotic signaling;
- LTI-01, a proenzyme that completed a Phase 2a dose-ranging, placebo-controlled trial and a Phase 1b safety, tolerability and proof of mechanism trial in loculated pleural effusion, or LPE, patients, an indication that has no approved drug treatment; and
- preclinical programs targeting cystic fibrosis and a peptide program focused on the Cav1 protein for systemic fibrosis indications.

In June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 and until additional funds are raised. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 and preclinical programs targeting cystic fibrosis and a peptide program focused on the Cav1 protein for an indefinite period.

Principal Product Candidates

LTI-03

LTI-03 is a novel peptide drug, the sequence of which is derived from the endogenous protein Cav1, that protects lung epithelial cells and inhibits multiple pro-fibrotic pathways in IPF patients. IPF is a progressive, fatal, age-associated lung disease with a median survival from diagnosis of three to five years. There are approximately 100,000 people living with IPF in the U.S. LTI-03 has been granted Orphan Drug Designation in the U.S. and European Union, or EU, for the treatment of IPF.

The pathogenesis of IPF is characterized by the loss of healthy lung cells known as alveolar epithelial type 2 cells, or AEC2s, proliferation and accumulation of activated myofibroblasts, deposition of extracellular matrix, or ECM, and fibrosis, resulting in labored breathing and loss of lung function. Damaged AEC2s are unable to replace injured alveolar epithelial type 1 cells, or AEC1s, which make up the majority of the alveolar surface and are important in mucus clearance and healthy lung function. Other than lung transplantation, no treatment has shown survival benefit. Three approved drugs, Nerandomilast (Jascayd®), nintedanib (OFEV®) and pirfenidone, have been shown to reduce the rate of lung function decline, but unfortunately provide only modest clinical benefit in IPF patients. No drug is curative, and significant side effects or intolerance can occur with the use of these therapies. As these approved drugs are focused on fibroblast proliferation, they have not demonstrated an effect on protecting or restoring healthy lung epithelial cells. We believe LTI-03 has a mechanism that not only reduces fibroblast proliferation but also, importantly, protects and potentially restores healthy lung epithelial cells.

Cav1 normally serves a critical function in the prevention of fibrosis by maintaining a balance between pathways that both initiate and arrest lung repair and cell movement. Studies conducted by third parties have shown decreased levels of Cav1 in patients with IPF and the development of fibrosis in Cav1 knock-out models of fibrosis. Furthermore, we have conducted in vitro and animal model tests with LTI-03 in which we have observed a reduction in numerous pro-fibrotic signaling proteins. In analyzing fibrotic activity in a sample precision cut lung slice, or PCLS, tissue from an end stage IPF lung, LTI-03 demonstrated a broad anti-fibrotic activity similar to that of nintedanib in a single patient sample and composite of six patient samples.

In additional PCLS testing of end stage IPF lungs with LTI-03, we observed increased viable AEC2s that are important for epithelial regeneration and proper lung function. We believe that this protection of AEC2s has the potential to improve IPF patients' underlying disease.

The soluble Receptor of Advanced Glycation End-products, or sRAGE, is a prognostic marker of IPF disease progression and is produced by AEC1s. Low levels of sRAGE at diagnosis predict poor survival in IPF and as IPF patients' disease worsens, sRAGE declines. In further testing of PCLS tissue, LTI-03 administration demonstrated an increase in sRAGE versus untreated control samples. We believe the increase in sRAGE provides further evidence of increased AEC2 survival, possibly leading to greater AEC1 production and thus overall epithelial cell survival, and therefore the elevation of sRAGE levels after administration of LTI-03 in the PCLS model may indicate a beneficial impact of LTI-03 in treating IPF patients.

Phase 1a Clinical Trial

We completed a randomized, double-blind, placebo-controlled, Phase 1a clinical trial of LTI-03 in healthy volunteers in the United Kingdom, or the UK. The primary objective of this trial was to determine the safety and tolerability of single and multiple ascending doses, SAD and MAD, respectively, of inhaled LTI-03. The secondary objective was to evaluate the pharmacokinetics of SAD and MAD daily doses for 14 days of inhaled LTI-03.

In four SAD cohorts, 32 subjects were administered LTI-03 by inhalation at single doses of 20 mg, 40 mg, and 80 mg. At the 80 mg dose, subjects in one cohort were administered four 20 mg capsules by inhalation and in a second cohort, subjects were administered eight 10 mg capsules by inhalation. Eight subjects in the combined SAD cohorts were administered a placebo. In the SAD cohorts, 21 of 24 subjects administered LTI-03 experienced treatment emergent adverse events, or TEAE, the most frequent of which were mild dry coughs related to LTI-03.

In two MAD cohorts, 40 subjects were administered LTI-03 by inhalation once daily for up to 14 days at 20 mg and 40 mg. Mild coughs, assessed as related to LTI-03, were the most frequent TEAEs occurring in 12 of 12 subjects over the course of the 14-day dosing period. Mild and related coughs occurred in three of the four subjects administered placebo. Other TEAEs occurring in more than one of the 12 subjects administered LTI-03 included sinus tachycardia, which is a fast increase in heart rate, in two subjects assessed as mild and not related in one and moderate and related in the other; chest discomfort in two subjects assessed as related and moderate in one and related and severe in the other; and labored breathing in two subjects assessed as related and moderate in one and related and severe in the other. During dosing in the second MAD cohort of 40 mg of LTI-03, we placed the study on hold after one subject developed severe TEAEs and two other subjects developed moderate TEAEs secondary to pulmonary airflow limitations that appeared to be secondary to reversible airway obstruction. These events were considered related to LTI-03. All TEAEs were resolved within 24 hours.

Adverse findings in the MAD 40 mg cohort, and a re-evaluation of the dose rationale based on further analysis of in vitro and in vivo data, suggest that lower doses should be efficacious with an improved safety profile. The 20 mg and 40 mg doses evaluated are predicted to be 21- to 39-fold in excess of a minimally efficacious dose. Based upon these MAD observations, three additional MAD cohorts of 2.5 mg administered once daily, 5 mg (two 2.5 mg capsules), and 10 mg (two 2.5 mg capsules dosed twice daily) were administered to 17 subjects for 14 days. In these lower dose cohorts, the most common TEAEs related to LTI-03 were mild coughs in 41% of subjects. The only other TEAEs occurring in more than one subject was mild throat irritation in two subjects that were assessed as related to LTI-03. The were no moderate, severe, or serious TEAEs assessed as related to LTI-03.

Upon review of pooled plasma samples from patients in all Phase 1a cohorts up to 20 mg, there was an increase in sRAGE from day 13 treatment compared to pre-treatment for patients who received LTI-03 compared to patients who received placebo.

Phase 1b Clinical Trial

We conducted a randomized, double-blind, placebo-controlled, Phase 1b clinical trial of LTI-03 in IPF patients, which was conducted at 11 centers in the U.S., the UK, Belgium, Germany and Australia. We enrolled a total of 24 patients in the trial. In the trial, these patients had a bronchoscopy at a baseline screening followed by either LTI-03 or placebo twice a day for 14 days. On day 14, shortly after the final dose, patients received a second bronchoscopy and were monitored thereafter for seven days. In Cohort 1, patients in the active arm inhaled a single 2.5 mg capsule of LTI-03 twice daily. In Cohort 2, patients received two 2.5 mg capsules of LTI-03 for inhalation twice daily. Of the 12 patients enrolled in Cohort 1 of the trial, three were randomized to the placebo arm and nine to the active arm.

Of the 12 patients enrolled in Cohort 1 of the trial, three were randomized to the placebo arm and nine to the active arm. In addition to the safety and tolerability of LTI-03, in the trial, various biomarkers relating to epithelial damage, fibrosis and inflammation in blood cells were assessed. The eight biomarkers that we evaluated in Cohort 1 included: thymic stromal lymphopoietin (TSLP), galectin-7 (GAL-7), interleukin-11 (IL-11), collagen 1 alpha chain (Col-1α1), phosphorylated SMAD2/3 (pSMAD2/3/tSMAD2/3), phosphorylated AKT kinase (pAKT), soluble (sol) receptor for advanced glycation end-products (solRAGE), and CXC chemokine 7 (CXCL7). The eight biomarkers that we evaluated in Cohort 2 included: TSLP, GAL-7, IL-11, Col-1α1, pSMAD2/3/tSMAD2/3, pAKT, CXCL7, and surfactant protein D (SPD). SolRAGE, which was evaluated in Cohort 1, was not able to be evaluated in Cohort 2 due to multiple protocol violations.

In May 2024, we announced positive data from the low-dose Cohort 1 of the Phase 1b clinical trial.

In Cohort 1, a positive trend was observed in seven out of the eight biomarkers with data from three biomarkers being statistically significant (based on a one-tailed t-test). The findings from Cohort 1 included:

- LTI-03 reduced expression of multiple profibrotic proteins in both pathologic basal-like cells and fibroblasts, with statistically significant decreases observed in three biomarkers - GAL-7 (p=0.0014, SEM 0.901), TSLP (p=0.0223, SEM 5.163) and Col-1α1 (p=0.0489, SEM 0.7102) - supporting the potential of LTI-03 to reduce fibrosis, inflammation and associated changes in the lung.
- LTI-03 stimulated production of solRAGE (p=0.1407, SEM 0.3269), a factor indicative of type I epithelial cell health that is a critically important aspect of IPF and has gone largely unaddressed.
- LTI-03 did not induce inflammation in peripheral blood mononuclear cells as measured by pAKT (p=0.358, SEM 11.32).
- LTI-03 was generally well-tolerated with no serious adverse events reported.

In November 2024, we announced positive topline data from the high-dose Cohort 2 of the Phase 1b clinical trial.

In Cohort 2, a positive trend was observed in seven out of the eight biomarkers, with data from three biomarkers that were statistically significant in Cohort 2, and from four biomarkers that were statistically significant in the combined data set of Cohort 1 and Cohort 2, and data from five biomarkers that showed dose dependence relative to the data from those biomarkers in Cohort 1. The findings from Cohort 2 included:

- LTI-03 reduced expression of multiple profibrotic proteins active in both pathologic basal-like cells and fibroblasts, with four biomarkers (IL-11, CXCL7, TSLP and GAL-7) showing statistically significant decreases in the combined data set supporting the potential of LTI-03 to reduce fibrosis, inflammation and associated functional changes in the lung.
- LTI-03 dose dependent trends were observed in five biomarkers, including COL1A1, CXCL7, TSLP, GAL-7, and SPD, which provide evidence of active LTI-03 pharmacodynamics in the trial.
- SPD, an indicator of epithelial cell health that is linked to decline in lung function, decreased by 5% in Cohort 2 at 14 days of treatment. The current standard of care for IPF, nintedanib, reduced SPD by 4% at 12-weeks in a third party trial of nintedanib referred to as the INMARK trial. The biomarker regarding change in SPD in our Phase 1b trial and the data from the INMARK trial of nintedanib compares two clinical trials with different trial designs, patient enrollment criteria and treatment regimens. In addition, the applicable measurements were observed over different time periods. As a result, the data from these trials may not be directly comparable.
- LTI-03 did not induce inflammation in peripheral blood mononuclear cells in either Cohort, measured by pAKT, a safety marker for inflammation in this trial.
- LTI-03 was generally well-tolerated, and there were no drug-related adverse events that resulted in a discontinuation of the trial.

Phase 2 Clinical Trial

In May 2025, we initiated screening and recruitment of patients in the RENEW Phase 2 clinical trial of LTI-03. The RENEW trial is a Phase 2 multi-center, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, and efficacy of LTI-03 patients with IPF. In addition, the trial is designed to assess the activity of inhaled dry powder LTI-03 across multiple biomarkers and to measure lung function, lung imaging markers of fibrosis, and the potential for healthy tissue regeneration. The trial is designed to enroll approximately 120 patients diagnosed with IPF within 5 years of screening, who may be receiving standard of care antifibrotic therapy, across up to 50 sites globally, including sites in the U.S., UK, Germany, Australia and Poland. Patients will be randomized into two blinded placebo-controlled cohorts that will run concurrently. Patients in the low dose cohort will receive 2.5 mg of either LTI-03 or placebo administered twice daily, or BID, for a total dose of 5 mg/day, while participants in the high dose cohort will receive 5 mg BID for a total dose of 10 mg/day. The primary endpoint is the incidence of treatment-emergent adverse events from Day 1 through Week 24. The key secondary endpoint is the efficacy of LTI-03 measured through forced vital capacity, percent predicted FVC and high-resolution computer tomography, in collaboration with Qureight Ltd. Patients will undergo a 28-day screening period prior to being randomized and entering the 24-week treatment period, with a four-week follow-up.

In October 2025, we received authorization from the European Medicines Agency, or the EMA, to initiate our Phase 2 RENEW trial of our lead candidate, LTI-03, for the treatment of IPF at sites in Germany and Poland. We had previously received regulatory clearance from the UK's Medicines and Healthcare products Regulatory Agency, or the MHRA. In January 2026, we received orphan drug designation from the EMA for LTI-03.

As of the date of this Annual Report, we activated sites and are enrolling patients in the U.S. and are seeking to activate additional sites, enroll patients and initiate the RENEW trial throughout the U.S., UK, Europe and other jurisdictions. In March 2026, we dosed our first patient in the RENEW Phase 2 clinical trial of LTI-03. We expect to report initial interim topline data on some proportion of patients in the fourth quarter of 2026.

LTI-01

LTI-01 is a single chain urokinase plasminogen activator, or scuPA, for the treatment of LPE. Pleural effusion is defined by the build-up of fluid in the pleural cavity, predominantly resulting from pneumonia, and is considered loculated when fibrinous scar tissue forms, trapping the fluid and preventing drainage. LPE is an orphan disorder for which there are no currently approved therapeutics. LPEs are a frequent complication of pneumonia and develop from pockets of infected fluid, known as a complicated parapneumonic effusion, or CPE, or if pus is present, known as an empyema. LPEs can result in pain, shortness of breath and can rapidly lead to sepsis and death. CPE and empyema can be serious clinical problems which are associated with mortality of approximately 20%. Effective drainage of infected pleural effusions is essential for treatment. We believe over 60,000 cases of LPE associated with CPE and empyema are estimated to occur annually in the U.S. alone, and based upon our market research, over half of these patients are receiving off-label, intrapleural fibrinolytic therapy, or IPFT, which is the use of clot busting drugs injected locally into the pleural cavity to treat the LPEs. LTI-01 has been granted Orphan Drug Designation in the U.S. and EU for treatment of empyema and Fast Track Designation in the U.S. for the investigation of LTI-01 for the treatment of infected, non-draining pleural effusion. In November 2020, we signed a regional licensing deal with Taiho for the rights to develop and commercialize LTI-01 in Japan. We received an up-front payment of $5.0 million and have the right to receive a future milestone payment of $10.0 million, drug supply payments and royalties on drug sales upon approval and commercial launch in Japan.

Currently, there are no approved drug treatments for LPE. Given the risks of surgery and extensive days of hospitalization post-surgery, IPFT has been used off-label in patients with LPE to promote pleural drainage. Despite limited research of IPFT, tissue plasminogen activator, or tPA, in combination with recombinant deoxyribonuclease, or DNase, has become the off-label standard of care for treating LPEs in many institutions. Similar to off label IPFT, LTI-01 works locally in the pleural space by breaking down the fibrinous scar tissue and allowing the trapped fluid to drain. We believe there are advantages possessed by LTI-01 over other fibrinolytics which arise from the resistance of LTI-01 to a protein which is the major inhibitor of fibrinolytic activity, Plasminogen Activator Inhibitor-1, or PAI-1. PAI-1 has been shown to suppress fibrinolytics like tPA by binding to them and inhibiting activity. LTI-01, however, has demonstrated relative resistance to PAI-1 inhibition. Animal model studies, conducted by third parties, of PAI-1 inhibition showed LTI-01 to be active 24 hours post administration, while tPA was shown to be inactivated in as little as 40 minutes. We believe that this provides for a longer duration of activity, eliminates the need for repeated daily dosing, and could confer a lower risk of bleeding.

Based upon our Phase 2a and Phase 1b data and historical treatment data of LPE patients receiving off-label tPA with DNase in the U.S., we believe LTI-01 may be more beneficial to patients when compared to tPA with DNase in the treatment of LPE on dosing schedule, surgical referrals and safety profile. Furthermore, third party market research with physician interviews performed by MME, a wholly-owned subsidiary of Indegene, Inc., suggests LTI-01 could potentially replace the use of tPA with DNase for LPE patients.

Phase 2a Clinical Trial

We completed a randomized, double-blind, placebo-controlled, Phase 2a clinical trial that was conducted at 36 centers in the U.S. to evaluate LTI-01 in patients with infected, non-draining pleural effusions. The primary endpoint in the trial was treatment failure, defined as death or referral to surgery by checklist within seven days from commencement of dosing. Secondary endpoints included length of hospital stay, incidence of bleeding and pain and volume of pleural fluid drainage. The trial evaluated 3 doses of LTI-01, 400,000, 800,000 or 1.2 million units compared to placebo in a three to one active to placebo randomization. Due to trial delays related to the COVID-19 pandemic and limited shelf life of drug product, only 40 patients completed enrollment in the trial. There was not a statistically significant difference in the primary endpoint of treatment failure between treatment arms and the placebo arm. We believe this lack of significance was due to referral to surgery checklist limitations which allowed patients, including those on placebo, to be deemed a successful treatment while also receiving rescue treatment, defined as either surgery, off label IPFT or other intervention. Based upon a patient's need for a rescue treatment, either surgery, off label IPFT or other intervention, 60.0% and 55.5% of patients in the 400,000 and 800,000 dosing arms, respectively, did not require rescue treatment to resolve their LPE. However, 27.3% of patients in the placebo dosing group did not require a rescue treatment to resolve their LPE. Moreover, the 400,000 and 800,000 dosing arms showed a meaningful reduction in volume of pleural fluid drainage, a secondary endpoint. LTI-01 was well tolerated with no safety signals of concern.

Based on the results of this trial, we plan to investigate LTI-01 in an additional Phase 2 dose-ranging, placebo-controlled clinical trial with a lower dose to establish efficacy and safety. In June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 and until sufficient additional funds are raised. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, as a result of our current capital limitations, we have suspended development activities for LTI-01 for an indefinite period and are allocating our limited resources to LTI-03 development.

Phase 1b Clinical Trial

We completed a first-in-human, open-label, dose escalation Phase 1b safety, tolerability and proof of mechanism trial of LTI-01 in 14 LPE patients presenting with pneumonia and CPE or empyema. The Phase 1b clinical trial was conducted at seven clinical centers in Australia and New Zealand. LTI-01 was administered intrapleurally once per day for up to three consecutive days at doses ranging from 50,000 units to 800,000 units. At the doses tested, LTI-01 was well tolerated and there were no safety signals of concern. Moreover, no local or systemic bleeding was observed. All adverse events observed were considered unrelated to the study drug.

LTI-01 showed preliminary signs of efficacy, with reductions in pleural opacity and declines in pleural infection indicators. Preliminary efficacy findings included signs of successful treatment of the underlying infectious process with decreased C-reactive protein, or CRP, levels and total leukocyte and neutrophil counts, drainage of the infected pleural fluid and decreases in pleural opacity. These results suggest that LTI-01 clears scar tissue with once-a-day dosing for three days and promotes fluid drainage around the lungs without bleeding and other side effects.

Preclinical Programs

We have multiple programs in preclinical development. We are developing LTI-05, an epithelial sodium channel, or ENaC, inhibitor, in lead optimization for the treatment of cystic fibrosis, or CF, that has demonstrated sodium channel inhibition and localized activity in preclinical studies. In addition, we are developing a systemic formulation of a proprietary Cav1-related peptide to be utilized for patients where a systemic delivery would be ideal. Cav1, from which LTI-03 is derived, has been widely studied for its role in the regulation of cell signaling and endocytosis and, we believe, restores balance by regulating aberrant cell signaling. Cav1 has been demonstrated to be deficient in multiple fibrotic organs in preclinical models. Independent preclinical research and our preclinical research have demonstrated the potential of a Cav1-related peptide to treat fibrosis in a number of organs, including kidney,

heart and skin. This preclinical program is currently in the formulation development stage. Similar to the LTI-01, we have suspended any development activities for our preclinical programs until we can raise sufficient financing and are allocating our limited resources to development of LTI-03.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely, on third-party contract manufacturers for the manufacture of all our product candidates for preclinical research and clinical trials. We do not have long-term agreements with any of these third-party contract manufacturers.

If any of our product candidates are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of our product candidates. Development and commercial quantities of any drugs that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA, and the regulatory agencies of other jurisdictions in which we are seeking approval.

The risks associated with our reliance on third-party contract manufacturers are described in Item 1A. Risk Factors - Risks Related to Our Dependence on Third Parties in this Annual Report on Form 10-K.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. We may seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we expect that the geographic market for a product we develop on our own is limited or that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific personnel provide us with competitive advantages, we face substantial competition from many different sources, including larger pharmaceutical companies with greater resources. Smaller specialty biotechnology and biopharmaceutical companies, academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies, including through collaborative arrangements with large and established biopharmaceutical companies. We also face competition in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling patients for clinical trials, and acquiring technologies complementary to, or necessary for, our programs. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, method of administration, cost, level of promotional activity and intellectual property protection.

There are a number of large biopharmaceutical and biotechnology companies that are currently pursuing the commercialization or development of products for the treatment of fibrosis. Companies that we are aware of that are targeting the treatment of various fibrosis indications include larger companies with significant financial resources such as AbbVie Inc., Boehringer Ingelheim GmbH, Bristol Myers Squibb Company, Gilead Sciences, Inc., Roche Holding AG, and Novartis AG. However, we know of no other companies currently in clinical development with a drug therapeutic utilizing Cav1 and Cav1-related peptides.

Although our novel approach is unique from most other existing or investigational therapies across the disease areas where we are focusing our development, we will need to compete with currently approved therapies, and potentially those currently in development if they are approved. We are aware of several marketed and investigational products in our leading disease areas, including but not limited to:

- IPF: There are currently three approved branded products for the treatment of IPF; Esbriet (pirfenidone), marketed by Roche Holding AG, and Ofev (nintedanib) and Jascayd (nerandomilast), both marketed by Boehringer Ingelheim GmbH. Companies currently developing product candidates in IPF include AbbVie Inc., Boehringer Ingelheim GmbH, Bristol Myers Squibb Company, Avalyn Pharma, Inc., Vicore Pharma Holding AB, Endeavor BioMedicines and PureTech Health plc.
- LPE: There are currently no approved drug therapies for the treatment of LPE. Roche Holding AG manufactures tPA and DNase, which are used off-label to treat LPE. We are not aware of any other pharmaceutical or biotechnology company developing drug therapies for the treatment of LPE.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our product candidates, if approved for marketing. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Out-License Agreement

Agreement with Taiho Pharmaceutical Co. Ltd.

On November 12, 2020, we entered into a license agreement with Taiho, or the Taiho Agreement, to collaborate on the development and potential commercialization of LTI-01. Under the terms of the Taiho Agreement, we granted Taiho an exclusive, royalty-bearing license to develop, seek regulatory approval for and commercialize LTI-01 in Japan. We are obligated to conduct all development activities for LTI-01 through regulatory approval in the U.S. or other markets worldwide, except Japan, and retain the right to commercialize LTI-01 in all markets worldwide except Japan. Under the terms of the Taiho Agreement, we, in part through our participation in a joint development committee with Taiho, will participate in overseeing the development and commercialization of LTI-01 in Japan.

In consideration for the exclusive, royalty-bearing license and other rights contained in the Taiho Agreement, Taiho made a non-refundable, non-creditable payment to us of $5.0 million. We are also eligible to receive an additional milestone payment of $10.0 million.

We are entitled to receive a minimum percentage on product sales for commercial supply and royalties. In addition, we are entitled to receive royalties on net sales of LTI-01 in Japan. Royalties will be payable during the period commencing on the first commercial sale of LTI-01 in Japan and ending upon termination or expiration of the Taiho Agreement.

Unless earlier terminated, the Taiho Agreement will expire on the later of (i) 10 years after the date of first commercial sale of LTI-01 in Japan, (ii) the expiration of the last valid intellectual property claim of any of our patents, if any, that covers LTI-01 in Japan and (iii) the expiration of the regulatory data exclusivity in Japan. Taiho has the ability to extend the term of the Taiho Agreement upon notice at least 12 months prior to the expiration of the initial term. Upon this extension notice, we and Taiho will negotiate a revised minimum supply transfer price, royalty and length of the extension term. Taiho has the ability to terminate the Taiho Agreement early for safety reasons or if marketing approval in Japan has not occurred within three years of initial filing for approval in Japan.

In-License Agreements

Agreement with the University of Texas Health Science Center at Tyler

In June 2013, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System, or UT System, on behalf of the University of Texas Health Sciences Center at Tyler, or UTHSCT. The patent and technology license agreement with UT System, or the UTHSCT Agreement, provides us

access to patents and technology related to the development of LTI-01 and LTI-03. As part of the UTHSCT Agreement, we have (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell certain intellectual property; (ii) a non-exclusive license under the technology rights to manufacture, distribute and sell the licensed product; and (iii) a sublicensing right that allows us to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the UTHSCT Agreement. In December 2013, the UTHSCT Agreement was amended and restated to include certain patents in all fields worldwide. In May 2017, the UTHSCT Agreement was amended and restated to modify the specific milestone criteria.

In consideration of the UTHSCT Agreement, we agreed to pay past and ongoing patent expenses, and we are obligated to pay UTHSCT sublicensing fees, assignment fees, and single digit royalties on worldwide net product sales, with fixed minimum royalty payments that started in 2015.

Pursuant to the UTHSCT Agreement, we are required to use diligent efforts to commercialize the licensed technology as soon as commercially practicable, including maintaining active research and development, regulatory, marketing and sales program, all as commercially reasonable.

We may terminate the UTHSCT Agreement for convenience with 90 days' notice. UTHSCT may also terminate the UTHSCT Agreement, but only if we breach the terms of the agreement. We incurred $0.1 million in a minimum royalty fee during the years ended December 31, 2025 and 2024, respectively.

Agreement with the University of Texas at Austin

In May 2015, we entered into a patent license agreement with the University of Texas at Austin, or UT Austin, on behalf of UT System. This license agreement with UT Austin, or the UT Austin 6607 Agreement, relates to the patent rights to polypeptide therapeutics and uses thereof. Pursuant to the UT Austin 6607 Agreement we have (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell the licensed product; and (ii) a sublicensing right that allows us to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. The UT Austin 6607 Agreement was amended and restated in January 2017, November 2018, and June 2019. The amendments related to extension of milestone payment dates and specific terminology around the milestone achievement criteria.

In consideration of the UT Austin 6607 Agreement, we agreed to pay past and ongoing patent expenses, milestone fees upon certain development and regulatory milestone events, annual license fees, tiered sublicense fees, assignment fees, low single digit royalties on net sales and the FDA Priority Review Voucher fee if we sell or transfers this voucher.

Pursuant to the UT Austin 6607 Agreement, we are required to use diligent efforts to commercialize the licensed products, including maintaining active research and development, regulatory, marketing and sales program. Moreover, we are required to meet certain development and regulatory milestones by specific dates.

We may terminate the UT Austin 6607 Agreement for convenience with 90 days' notice. UT Austin may also terminate the UT Austin 6607 Agreement, but only if we breach the terms of the agreement. We did not incur any expenses under the UT Austin 6607 Agreement during the years ended December 31, 2025 and 2024.

Agreement with Medical University of South Carolina

In March 2016, we entered into a license agreement with Medical University of South Carolina Foundation for Research Development, or MUSC. Pursuant to this license agreement with MUSC, or the MUSC Agreement, we have patent rights related to protecting against lung fibrosis by up-regulating Cav1. The MUSC Agreement granted (i) a royalty-bearing, exclusive license under the patent rights to make, use and sell the license product; and (ii) a sublicensing right that allows us to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. In September 2018, the agreement was amended and restated to include definitions of related methods, related products and related rights.

In consideration of the MUSC Agreement, we agreed to pay a non-refundable license fee, patent expenses, milestone fees upon certain development, regulatory and commercial milestone events, sublicense fees, assignment fees and low single digit royalties on net sales, with a fixed minimum royalty payment starting in 2019 and a transaction fee upon our liquidation.

Pursuant to the MUSC Agreement, we are required to use diligent efforts to develop, manufacture and sell the licensed products.

We may terminate the MUSC Agreement for convenience by providing a written notice to MUSC effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. We incurred $25 thousand in a minimum royalty fee during the years ended December 31, 2025 and 2024.

Agreement with Vivarta Therapeutics LLC

In March 2018, we entered into a license agreement with Vivarta Therapeutics, LLC, or Vivarta. This license agreement with Vivarta, or the Vivarta Agreement, relates to intellectual property relating to epithelial sodium channel inhibitors and methods to treat pulmonary disease. Pursuant to the Vivarta Agreement we have (i) a royalty-bearing, exclusive license under the intellectual property rights to make, use and sell the licensed product, and (ii) a sublicensing right that allows us to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement.

In consideration of the Vivarta Agreement, we also agreed to pay patent expenses, milestone fees upon certain development and regulatory milestone events, sublicense fees, assignment fees and low single digit royalties on net sales.

Pursuant to the Vivarta Agreement, we are required to use diligent efforts to develop, manufacture and sell the licensed products.

We may terminate the Vivarta Agreement for convenience by providing a written notice to Vivarta effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. We did not incur any expenses under the Vivarta Agreement during the years ended December 31, 2025 and 2024.

Intellectual Property

Overview

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to our proprietary pipeline of product candidates and on know-how, continuing technological innovation and in-licensing opportunities to develop and strengthen our pipeline that may be important for the development and growth of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions, where available.

Our commercial success may depend in part on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, enforcement of these rights may depend on third party licensors. With respect to both licensed and company-owned intellectual property, 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 of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

As of March 24, 2026, we own or have licensed fifty-eight issued patents and fifty-two pending patent applications worldwide, which are material to the programs described below relating to the Lung business. Forty-six issued patents worldwide and five pending patent applications are owned by the UT System, which have granted us exclusive license rights to the technology. We own five issued patent and ten pending patent applications worldwide together with the UT System, which have granted us exclusive license rights to the technology. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We seek U.S. and foreign patent protection for a variety of technologies, including caveolin-1 peptides, such as LTI-03, compositions, and formulations related to caveolin-1 peptides, methods for therapeutic use of caveolin-1 peptides and conjugates of interest and diagnostic methods with caveolin-1 peptides for treating diseases of interest. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and identify and develop novel products. We seek protection, in part, through confidentiality and proprietary information agreements. We are a party to various other license agreements that give us rights to use specific technologies in our research and development.

LTI-03 Program

As of March 24, 2026, we owned two U.S. patents, including U.S. Patent Nos. 12,280,088 and 12,280,089, three patents granted outside of the U.S., nine pending U.S. patent applications, and twenty-eight pending applications outside of the U.S. related to the LTI-03 program. We also have licensed: six U.S. patents, including U.S. Patent Nos. 8,697,840, 9,630,990, 10,377,796, 11,161,875, 11,780,879, and 12,173,089, forty patents granted outside of the U.S., one pending U.S. application, and four pending applications outside of the U.S. related to the LTI-03 program. The issued LTI-03 related patents are expected to expire between the years 2030 and 2041, without any available patent term extensions. Patents that may issue from the pending applications are expected to expire between the years 2034 and 2044, without any available patent term extensions. The issued patents we own with the UT system are directed to dry powder formulations of LTI-03 and therapeutic uses thereof. The in-licensed LTI-03 issued patents from the UT System are directed to methods of treating acute lung injury or pulmonary fibrosis with LTI-03 and methods of treating a condition characterized by fibrosis with LTI-03. The pending applications in the LTI-03 program are directed to methods for treating diseases or disorders, including fibrosis, methods for increasing viability of lung epithelial cells, and formulations, including dry powder and extended-release formulations, as well as therapeutic uses of LTI-03 for other indications interest and diagnostic methods.

As of March 24, 2026, we also own three U.S. patents, four patents granted outside of the U.S., one pending U.S. application, and nine pending applications outside of the U.S. related to other caveolin-1 peptides related to LTI-03. These patents and patents that may issue from these pending applications are expected to expire in 2039.

U.S. Government Regulation of Drug and Biological Products

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of drugs and biologics. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance are often revised or reinterpreted by government agencies in ways that may have a significant impact on our business.

In the U.S., the FDA approves and regulates drug products under the Federal Food, Drug, and Cosmetic, or FDCA, and related regulations. Biological products, or biologics, are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations.

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the U.S. must satisfactorily complete the following steps, where applicable:

- completion of preclinical laboratory tests and animal studies according to good laboratory practices, or GLP, or other applicable regulations;
- manufacture and testing of the therapeutic or biologic moiety and its respective product formulation according to good manufacturing practices, or cGMP, or other applicable regulations;
- design of a clinical protocol and submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an independent institutional review board, or IRB, or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational drug product and the safety, purity and potency for the investigational biologic product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA requesting marketing approval for one or more proposed indications;
- payment of application and program fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- review of the NDA or BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug or biologic and its respective finished product is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the NDA or BLA; and
- the FDA review and approval of the NDA or BLA authorizing marketing of the drug or biological product for particular indications in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any other potential post-approval studies required by the FDA.

Preclinical Studies and IND

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry/biology, formulation and stability, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety and toxicology studies. The sponsor must submit the results of the preclinical studies, 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. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application and are typically referred to as IND-enabling studies.

An IND is a request for authorization from the FDA to administer an investigational product to humans. The IND sponsor must submit the IND and then wait 30 days before initiating clinical trials, so that FDA can use that time to review the submission, and raise concerns or questions related to one or more proposed clinical trials. Even if the FDA does not raise concerns within 30 days, it could place the clinical trial on a clinical hold due to, for example, potential safety concerns or CMC issues. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Imposition of a clinical hold could cause significant delays or difficulties in initiating and/or completing planned clinical trials in a timely manner. Certain long-term preclinical testing, such

as animal tests of reproductive adverse events and carcinogenicity, may initiate or continue after an IND for an investigational product candidate is submitted to the FDA and human clinical trials have been initiated.

Human Clinical Trials in Support of an NDA or BLA

Clinical trials involve the administration of an investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, inclusion and exclusion criteria, dosing procedures and the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol, as well as any subsequent amendments, must be submitted to the FDA as part of the IND.

An IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review of the trial. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects or their legal representatives and must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or, if the drug or biologic has been associated with unexpected serious harm to patients.

Clinical trials must also comply with extensive GCP standards intended to ensure protection of human subjects and the quality and integrity of the study data, including requirements for obtaining subjects' informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee, or DMC. This group may recommend continuation of the trial as planned, changes in trial conduct or cessation of the trial at designated checkpoints based on access to certain data from the study. The FDA may, at any time while clinical trials are ongoing, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order, if issued by the FDA, would cause suspension of an ongoing trial until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed.

Human clinical trials to evaluate therapeutic indications to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, and if possible, to gain early evidence for effectiveness. Phase 1 trials may be conducted in healthy volunteers or, in the case of some products for severe or life-threatening diseases, including many rare diseases, the initial human testing is often conducted in patients with the target disease or condition.
- Phase 2: Clinical trials are conducted in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: Clinical trials are undertaken with an expanded patient population to further evaluate dosage, and to provide substantial evidence of clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, or to document a clinical benefit in the case of drugs or biologics approved under the FDA's accelerated approval regulations and generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or

BLA. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for the product.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress began requiring sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for Diversity Action Plans, or DAPs. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health for public dissemination on the clinicaltrials.gov data registry. Similar requirements for posting clinical trial information in clinical trial registries exist in the EU and in other countries outside the U.S. As of December 19, 2024, the FDA has issued six notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10 thousand for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2 and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. From a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP regulatory requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. For biological products in particular, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined in order to help ensure safety, purity and potency.

Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and FDA Review

Assuming successful completion of the required clinical testing, the results of the clinical trials and preclinical studies (along with information relating to the product's chemistry, manufacturing, controls, or CMC) and the proposed labeling are submitted to the FDA as part of an NDA or BLA, requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the FDA must find the data submitted to be sufficient to establish the safety and efficacy of the investigational drug product, and safety, potency and purity for the investigational biologic product, for its proposed indication. The fee required for the submission of an NDA or BLA under the PDUFA, is substantial (for example, for fiscal year 2026 this application fee is approximately $4.7 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, which is currently set at $0.4 million per eligible prescription program. These fees are adjusted annually, but exemptions and waivers may be available under certain circumstances. No user fee is required for orphan drug product applications, except when an application also includes an indication for a non-rare disease or condition.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor by that time whether an application is sufficiently complete to permit substantive review. In the event that the

FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date (following the 60-day validation period) in which to complete its initial review of a standard application and respond to the applicant and six months from the filing date for an application with "Priority Review". The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities, including the review of both NDAs and BLAs.

Before approving an NDA or BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the therapeutic/biologic to determine whether the manufacturing processes and facilities comply with GMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities comply with cGMP regulatory requirements and are adequate to ensure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to ensure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

Under certain circumstances, the principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Additionally, the FDA may refer any NDA or BLA, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA also may require submission of a REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS and the FDA will not approve the NDA or BLA without a REMS.

Under the Pediatric Research Equity Act of 2003, or PREA, an NDA or a BLA or certain supplements thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless this requirement is waived, deferred or inapplicable. Sponsors must submit a pediatric study plan to the FDA outlining the proposed pediatric study or studies they plan to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The FDA must then review the information submitted, consult with the sponsor, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. In general, PREA requirements do not apply to drugs or biologics for indications granted Orphan Drug Designation although the FDA has taken steps to limit what is considers abuse of this statutory exemption in the PREA by announcing that is does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease.

The FDA reviews an NDA or a BLA to determine, among other things, whether a product is safe and effective for its intended use, and whether its manufacturing is cGMP-compliant to ensure and preserve the product's identity, strength, quality and purity. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After evaluating the application and all related information (including the advisory committee recommendations, if any) and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a Complete Response Letter, or CRL.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings, or precautions be included in the product labeling (including specific safety-related label warnings). The FDA may also require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions, or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, and the FDA review and approval.

Expedited Programs for Serious Conditions

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include Fast Track Designation, Breakthrough Therapy Designation, Priority Review Designation and accelerated approval.

To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast Track Designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA also may review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. Fast Track Designation may be rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process. Fast Track Designation does not guarantee product approval.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy Designation if it 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 drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy Designation provides all the features of Fast

Track Designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and the FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate. Breakthrough Therapy Designation may be rescinded by the FDA if the designation is no longer supported. Breakthrough Therapy Designation does not guarantee product approval.

The FDA may designate a product for Priority Review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug or biologic qualifies for Priority Review. Significant improvement over available therapies may be illustrated, for example, by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A Priority Review Designation is intended to direct overall attention and resources to the evaluation of such applications and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or NDA from the date of filing.

Fast Track Designation, Breakthrough Therapy Designation and Priority Review do not change the standards for approval and may not ultimately expedite the development or approval process.

Finally, the FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (IMM), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs granted accelerated approval, the FDA generally requires sponsors to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless the FDA informs the applicant otherwise.

With the passage of FDORA, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to the FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing the FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidance relating to accelerated approval. These guidance describe the FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval.

Post Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, governing, among other things, manufacturing and quality-related compliance, monitoring and recordkeeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations, known as off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies, including state regulatory bodies, actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain the FDA approval of a new NDA or a BLA or an NDA or a BLA supplement, which may require the applicant to develop additional data or conduct additional clinical trials and preclinical studies. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA regulations require that drug and biological products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP regulatory requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. In addition, for any of our product candidates that include a device delivery system, the device component will be subject to aspects of the Quality System Regulations (QSRs) applicable to medical devices.

Once an approval of a drug/biologic product is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained, or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market clinical trials requirement to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling, and issuance of corrective information;
- fines, warning letters, untitled letters, or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and

- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In September 2021, the FDA published final regulations that describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act (PIE) Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products and product candidates in development to help expedite patient access upon product approval. Previously, such communications were permitted under the FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products and product candidates in development to payors, including unapproved uses of approved products.

In addition, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, or HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Additionally, the Drug Supply Chain Security Act, or DSCSA, imposes requirements related to identifying and tracing certain prescription drugs distributed in the U.S., including most biological products. Manufacturers were required by November 2023 to have such systems and processes. So as not to disrupt supply chains, the FDA has granted certain exemptions from enhanced drug distribution security requirements for eligible trading partners for particular periods of time.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of the FDA approval for our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date, and only those claims covering such approved drug

product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or a BLA, plus the time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Generic Drugs and Regulatory Exclusivity for Drug Products

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and effectiveness for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference or use from the person by or for whom the investigations were conducted".

In addition, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, a sponsor must submit an abbreviated new drug application, or ANDA, to the FDA. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of 505(b)(2) applications and ANDAs. The FDCA provides a five-year period of regulatory exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or a 505(b)(2) NDA submitted by another company for another version of such drug. However, an application may be submitted after four years if it contains a certification of patent invalidity, non-infringement, or unenforceability for the listed drug.

The FDCA also provides three years of regulatory exclusivity for a full NDA, 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving competitor products for drugs that fall outside the scope of the exclusivity. Three-year exclusivity will not delay the submission or approval of a full NDA; it delays approval of a 505(b)(2) NDA or an abbreviated new drug applications. or ANDA, covered by the exclusivity, until the exclusivity expires, but not the submission itself.

Biosimilars and Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the U.S. and included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product.

To date, the FDA has approved a number of biosimilars and several interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product". In order for FDA to approve

a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from analytical studies showing that the biosimilar product is highly similar to the reference product, data from animal studies (including toxicity) and data from one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

The BPCIA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

The FDA maintains a publicly-available online database of licensed biological products, which is commonly referred to as the “Purple Book”. The Purple Book lists product names, dates of licensure, and applicable periods of exclusivity. Further, the reference product sponsor must provide patent information and patent expiry dates to the FDA following the exchange of patent information between biosimilar and reference product sponsors. This information is then published in the Purple Book.

There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Orphan Drug Designation in the U.S. is designed to encourage sponsors to develop products intended for the treatment of rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the U.S.

Orphan Drug Designation qualifies a company for certain tax credits. Designation does not guarantee approval. In addition, if a product candidate that has Orphan Drug Designation subsequently receives the first FDA approval for that drug for the disease for which it has such designation, the product may receive seven-year orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior. Absent a showing of clinical superiority, the FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities.

A sponsor may request Orphan Drug Designation of a previously unapproved product or new orphan indication for an already marketed product. More than one sponsor may receive Orphan Drug Designation for the same product for the same rare disease or condition, but each sponsor seeking Orphan Drug Designation must file a complete orphan disease designation application. To qualify for orphan exclusivity, however, the drug must be clinically superior to the previously approved product that is the same drug for the same condition. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

LTI-01 has been granted Orphan Drug Designation by the FDA and European Medicines Agency, or EMA, for the treatment of pleural empyema. LTI-03 has been granted Orphan Drug Designation by the FDA and EMA for treatment of IPF.

Pediatric Exclusivity

Pediatric exclusivity is another type of regulatory exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of regulatory exclusivity. For drug products, the six-month period of exclusivity may be attached to the term of any existing patent or regulatory exclusivity. For biologic products, the six-month period may only be attached to any existing regulatory exclusivities but not to any patent terms. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data.

Regulation Outside of the U.S.

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain the FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member EU, before we may commence clinical trials or market products in those countries or areas.

With the exception of the EU or European Economic Area, or EEA, applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain the FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union Drug Development, Review and Approval

In the EU, our product candidates are subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

The Clinical Trials Regulation (EU) No 536/2014, which came into application on January 31, 2022, governs the system for the approval of clinical trials in the EU.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure continues to be governed by the

national law of the concerned EU Member State. However, overall related timelines have been defined by the Clinical Trials Regulation.

The extent to which clinical trials, which were ongoing on January 31, 2022 are governed by the Clinical Trials Regulation depends on the date when the request for authorization of a clinical trial has been submitted and on the duration of the individual clinical trial. Generally, according to the transitional provisions, if the request for authorization of a clinical trial has been submitted before the date of application of the Clinical Trials Regulation (i.e. before January 31, 2022) and the clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable (i.e. beyond January 31, 2025), the Clinical Trials Regulation will at that time begin to apply to the clinical trial. Until then the predecessor provisions of the Clinical Trials Directive 2001/20/EC, Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States apply.

If any of our product candidates that, if used separately, would be considered a medicinal product is incorporated, as an integral part, in a medical device intended to administer the medicinal product, and the action of the medicinal product is principal and not ancillary to that of the device, then the combination product is regulated by Directive 2001/83/EC or Regulation (EC) 726/2004 as a medicinal product. However, the medical device used for administration must satisfy the requirements for its general safety and performance under EU law governing general medical devices.

The EU regulatory regime under Directive 93/42/EEC, or the Medical Devices Directive, was replaced by Regulation (EU) 2017/745 on medical devices, or the Medical Devices Regulation as of May 26, 2021, subject to the transitional provisions for medical devices to remain on the EU market for a limited period if they were certified or, if certification was not required, the EU declaration of conformity had been drawn up under the Medical Devices Directive. There are significant changes to the EU regulatory system governing medical devices under the Medical Devices Regulation.

Under the Medical Devices Regulation, data resulting from the conformity assessment relating to the general safety and performance of the medical device that is part of a combination product regulated by Directive 2001/83/EC or Regulation (EC) 726/2004 shall be included in the application for marketing authorization for the combination product. Such information must be provided by the manufacturer of the medical device in its EU declaration of conformity, or the relevant certificate issued by a notified body allowing the medical device manufacturer to affix a European Conformity, or CE mark to the medical device. If the dossier submitted to support the marketing authorization for a combination product within the scope of Directive 2001/83/EC or Regulation (EC) 726/2004 does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with the Medical Devices Regulation, the medicinal products authority such as the EMA can require the applicant for a marketing authorization to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements issued by a designated notified body.

For marketing authorization applications, or MAA, the law provides for the so-called centralized authorization and authorization procedures in individual EU member states, whereas the Mutual Recognition or Decentralized procedure is mandatory for a product to be authorized in more than one EU member state.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the EMA that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway, which are part of the EEA. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell- therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/ AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA 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 Committee for Medicinal Products for Human Use, or CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The applicant may choose a member state as the reference member State to lead the scientific evaluation of the application.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State (which acts as the reference member state), in accordance with the national procedures of that country. Following this, further marketing authorizations can be progressively sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization produced by the reference member state.

Under the above-described procedures, before granting the marketing authorization, the competent authorities of the EU Member States have 90 days to review the assessment report rendered by the reference member state. Approval of the assessment report may be only denied for the reason of potential serious risk for public health. In case of diverging views among the member states, a coordination procedure at EU level applies, leading ultimately to a uniform decision binding on the member states.

On April 26, 2023, the European Commission presented a draft for a comprehensive reform of the pharmaceutical legislation. The so-called "EU pharmaceutical package" does not intend to change the existing procedures currently in place at EU level: Medicinal products are still to be approved in the decentralized procedure, mutual recognition procedure, or centralized procedure. However, the duration of authorization procedures is generally to be reduced. The decisive factor for the reduction of the duration of the procedure under the decentralized procedure and the mutual recognition procedure is the reduction of the period of cooperation of the EU member states. In regards of the centralized procedure, the shortening of the overall duration results from the accumulation of several small reductions in time.

Conditional Marketing Authorization

In specific circumstances, EU legislation enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. The legal basis is Article 14-a of Regulation (EC) No. 726/2004. The provisions for granting a conditional marketing authorization are further elaborated in Regulation (EC) No. 507/2006. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if the benefit-risk balance of the medicine is positive; it is likely that the applicant will be able to provide comprehensive data post-authorization; the medicine fulfils an unmet medical need; and the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. In a public health emergency, the conditional marketing authorization procedure can also be combined with a rolling review of data during the development of a promising medicine, to further expedite the evaluation.

European Union Regulatory Data Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The planned EU pharmaceutical package mentioned above foresees that pharmaceutical companies are given the opportunity to receive a period of protection of up to twelve (12) years (as opposed to the maximum of 11 years currently possible) by achieving certain public health objectives which are as follows:

- two (2) years extension if a pharmaceutical is placed on the market by a company in all Member States within two years, or within three years for companies with limited experience in the EU system;
- six (6) months extension if the medicinal product covers an unmet medical need;
- six (6) months extension if comparative clinical trials are conducted; and
- one (1) year extension if a new indication is authorized for the medicinal product within the protection period, provided that a significant benefit can be achieved in comparison with existing therapies.

European Union Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term 'significant benefit' is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. 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. This is determined by the molecular structure, the mechanism of action and the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. On the other hand, orphan market exclusivity

can be extended to a maximum of twelve years if an approved pediatric investigation plan (PIP) has been completed. Furthermore, marketing authorization may be granted to a similar product for the same indication at any time if:

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

The planned EU pharmaceutical package mentioned above provides, among others, for a new regulation to replace Regulation (EC) No. 141/2000 on orphan medicinal products. The draft regulation introduces the possibility of establishing new designation criteria by the EMA and the restriction of designation as an orphan drug to generally seven years. The draft regulation also provides for more flexible rules on the duration of market exclusivity, including: ten years of market exclusivity for orphan drugs in the case of "high unmet medical need", five years for orphan drugs, approved by a bibliographic marketing authorization and nine years in all other cases with the possibility of extension in the case of market access in all Member States (another year) or development of new therapeutic indications for an already authorized orphan medicinal product (up to two years). Market exclusivity can thus add up to a maximum of thirteen years, whereas today it is still capped at ten years. It should be noted that the market exclusivity right of the orphan medicinal product does not prevent the submission, validation and assessment of an application for marketing authorization of a similar medicinal product, including generics and biosimilars, if the remaining duration of the market exclusivity right is less than two years. The EU pharmaceutical package is still at an early stage of the legislative process. It may still undergo substantial changes and is expected to turn into binding law in several years' time.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

In future, under the planned EU pharmaceutical package mentioned above, pharmaceutical marketing authorizations are to be valid for an unlimited period, although a limitation of the duration to five years shall be possible in certain cases. The so-called sunset provision will be abolished.

Brexit and the Regulatory Framework in the United Kingdom

The UK's withdrawal from the EU, commonly referred to as Brexit, took place on January 31, 2020. The EU and the UK reached an agreement on their new partnership in the Trade and Cooperation Agreement, which entered into force on May 1, 2021. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol, as amended by the so called Windsor Framework agreed in February 2023. As of January 1, 2025, the changes introduced by the Windsor Framework resulted in the MHRA being responsible for approving all medicinal products destined for the United Kingdom market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU.

As of January 1, 2024 on, a new international recognition procedure, or IRP, applies which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or a mutual recognition and decentralized procedure, or MRDC, positive end of procedure outcome is an RR authorization for the purposes of IRP.

As with other issues related to withdrawal of the UK from the EU, there are open questions about how personal data will be protected in the UK and whether personal information can transfer from the European Union to the United Kingdom. Following the withdrawal of the UK from the EU, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by the EU General Data Protection Regulation, or GDPR. While the Data Protection Act 2018 in the UK that implements and complements the GDPR achieved Royal Assent in May 2018 and is now effective in the UK, it is still unclear whether transfer of data from the EEA to the UK will remain lawful under the GDPR. The UK government has already determined that it considers all EU and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the UK to the EU and EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the EU to the UK, although this decision may be re-evaluated in the future.

Rest of the World Regulation

For other countries outside of the EU, UK and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage, Pricing and Reimbursement

Sales of any biopharmaceutical products, if and when approved by the FDA or analogous authorities outside the U.S., will depend in significant part on the availability of third-party coverage and reimbursement for the products.

In the U.S., third-party payors include government healthcare programs such as Medicare and Medicaid, private health insurers, managed care plans and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including biopharmaceutical products. Significant uncertainty exists regarding coverage and reimbursement for newly approved healthcare products. Coverage does not ensure reimbursement. It is time consuming and expensive to seek coverage and reimbursement from third-party payors. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA regulatory approvals. Third-party payors may take into account clinical practice guidelines in determining coverage and there may be significant delays before our products are addressed by such guidelines and we cannot predict what position such guidelines would take with respect to our products if and when addressed. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, or utilize other mechanisms to manage utilization (such as requiring prior authorization for coverage for a product for use in a particular patient). Limits on coverage may impact demand for our products. Even if coverage is obtained, third- party reimbursement may not be adequate to allow us to sell our products on a competitive and profitable basis. As result, we may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, subject to the requirements set out in Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, EU Member States have the legal competence to set national measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products. Accordingly, EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use.

On December 13, 2021, a new Regulation on HTA was adopted by the EU. It entered into force in January 2022 and will become fully applicable in January 2025. The regulation provides for a coordinated approach to assessing the benefit of new therapies, which assessment will take place in parallel to the EU regulatory approval process. The objectives of the EU HTA regulation are to accelerate patient access to new therapies and reduce duplication of work. The impact of the new legislation on market access, pricing and reimbursement of new medicinal products in the individual EU countries cannot be predicted yet. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be significantly lower.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel import or distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. Health Care Laws and Regulations

In the U.S., biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which will apply only if and when we have an approved product, include:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the Travel Act of 1961, which has been used as a tool in the health care context to target kickback schemes involving private insurance that would not otherwise be prohibited under the anti-kickback statute, makes it unlawful for a facility to use interstate commerce with the intent, among other things, to distribute proceeds of "unlawful activity" and thereafter do some act to further such distribution ("unlawful activity" includes bribery under the state law in which the activity was committed); and
- laws and regulations prohibiting bribery and corruption, such as the U.S. Foreign Corrupt Practices Act or the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly.

Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Health Care Reform in the U.S.

The containment of health care costs has also become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States. In March 2010, President Obama signed into law the Affordable Care Act (ACA). In addition, other legislative changes have

been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (TCJA), which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate". The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. The nature and scope of health care reform in the second Trump administration remains uncertain but early actions suggest that efforts to undermine the ACA will be renewed and litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Price Reform

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of products from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA. On January 5, 2023, the FDA approved Florida's plan for Canadian product importation. That state now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. The state will also need to relabel the products and perform quality testing of the products to meet the FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors

were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022 (IRA) further delayed implementation of this rule to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Medicare Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Medicare Part D drugs in 2027, 15 Medicare Part B or Medicare Part D drugs in 2028, and 20 Medicare Part B or Medicare Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition.

On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, several other parties filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

At the state level, legislatures are increasingly 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. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright,

arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

For a more detailed discussion of health care reform in the U.S., see "Risk Factors - Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations."

Data Privacy Regulation

U.S. Privacy Law

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including laws requiring the safeguarding of personal information and laws requiring notification to governmental authorities and data subjects as well as remediation in the event of a data breach. In the health care industry generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended in 2009 by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. HITECH made significant modifications to HIPAA including subjecting business associates to direct regulation and enforcement by the Office of Civil Rights of HHS, or OCR, instituting a breach notification requirement for breaches of unsecured PHI, including a breach of PHI held by a business associate, and strengthening the enforcement tools available to OCR. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws.

General Data Protection Regulation

Many countries outside of the U.S. maintain rigorous laws governing the privacy and security of personal information. The GDPR became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the U.S., providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent to certain processing activities from the individuals to whom the personal data relates, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. The GDPR provides for substantial penalties to which we could be subject in the event of any non-compliance, including fines of up to €10.0 million or up to two percent of our total worldwide annual revenues, whichever is greater, for certain comparatively minor offenses, or up to €20.0 million or up to four percent of our total worldwide annual revenues, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers, and recent court decisions and regulatory guidance have substantially increased the compliance burden and legal uncertainty associated with transferring the personal data of

EEA individuals to third countries outside of the EEA whose data protection laws are not believed to be adequate by European standards (although the recent EU-US Data Privacy Framework offers a new route for data transfers from the EU to be made lawfully to the US).

Further, the GDPR provides for opening clauses in certain areas, which enable the legislators of member states of the EU to implement additional requirements to the GDPR in national law, whereby national laws may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA.

Also, as it relates to processing and transfer of genetic, biometric and health data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The UK's decision to leave the EU (and it is important to note that the EEA does not include the UK), often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK and to what extent UK law will diverge from the GDPR in the future. At this point in time, the UK Government has incorporated the GDPR into UK law, known as the 'UK GDPR', but has also published proposals recently to reform UK data protection law which are going through the UK Parliament and likely to become law in 2024. In the context of international data transfers, European Commission has issued adequacy decisions which have the effect of authorizing data transfers from the EEA to the UK. The UK Government and the Information Commissioner's Office have also published proposals recently to indicate how data transfers between the UK and the rest of the world will be regulated now that the UK has left the EU. For instance, the UK Government proposes recognizing more countries as adequate for data transfers as part of reducing barriers to data flows — this would include countries not yet authorized by the European Commission. The UK Government has also approved the UK Extension to the EU-US Data Privacy Framework for data transfers from the UK to the US.

Employees and Human Capital Resources

As of December 31, 2025, we had 10 full-time employees, including a total of two employees with M.D. or Ph.D. degrees. Of these full-time employees, four are engaged in research and development activities and six are engaged in general and administrative activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement.

We are dedicated to fostering a workplace environment that keeps our employees inspired, including providing a comprehensive benefits program that supports the health care, family, and financial needs of our employees. All of our full-time employees are eligible for cash bonuses and equity awards in addition to other benefits including comprehensive health insurance, life and disability insurance, and 401(k) matching.

Corporate Information

We were incorporated under the laws of the State of Delaware on August 6, 2001 under the name Renegade Therapeutics, Inc. We changed our name to Aileron Therapeutics, Inc. on February 5, 2007. On October 31, 2023, we acquired Lung Therapeutics, Inc., or Lung, pursuant to an Agreement and Plan of Merger, after which time Lung became a wholly owned subsidiary of ours. On January 10, 2025, we changed our name to Rein Therapeutics, Inc., and changed our trading symbol from "ALRN" to "RNTX", effective January 13, 2025. Our principal executive office is located at 12407 N. Mopac Expy. Suite 250 #390, Austin, TX 78758, and our telephone number is (737) 802-1989.

Information Available on the Internet

Our internet website address is http://www.reintx.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendment to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through the "SEC Filings" section of our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. We also make available, free of charge on our website, the reports

filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. You can review our electronically filed reports and other information that we file with the SEC on the SEC's website at http://www.sec.gov.

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10-K and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Condition

We require substantial additional capital to finance our operations. Our cash and cash equivalents are not sufficient to enable us to sustain our operations beyond the second quarter of 2026 or complete the development and commercialization of LTI-03. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our clinical and research and development programs, future commercialization efforts or other operations.

As of December 31, 2025, we had approximately $3.2 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2025, together with the $4.3 million of proceeds received by us pursuant to the securities purchase agreements we entered into in January and February 2026, will be sufficient to enable us to fund our planned operating expense and capital expenditure requirements into the second quarter of 2026. These funds are not sufficient to enable us to sustain our operations beyond the second quarter of 2026 or complete the Phase 2 RENEW clinical trial of LTI-03. Our future viability is dependent on our ability to raise additional capital to finance our operations within the next five months. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, or at all. If we are unable to obtain sufficient funding on terms acceptable to us, on a timely basis or at all, we may be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain, skilled personnel;

- the costs of operating as a public company;
- if our product candidates are approved, our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in businesses, products, and technologies; and
- unfavorable global economic conditions, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to LTI-03, LTI-01 or other product candidates.

We expect our expenses to increase as we will incur significant research and development expenses as we conduct planned clinical trials, continue our non-clinical research with our product candidates, initiate additional clinical trials of our product candidates and pursue later stages of clinical development of our product candidates. Until such time, if ever, as we can generate substantial revenues from the sale of our products, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our then existing stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. In addition, debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Securing financing may also require a substantial amount of time and attention from our management team and could divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We may seek one or more collaborators for future development of our product candidates for one or more indications. However, we may not be able to enter into such collaborations on suitable terms, on a timely basis, or at all. Even if we are able to raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce and/or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves.

We have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our prospects and likelihood of success.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing clinical trials and research and development of our main product candidate, LTI-03. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 for an indefinite period due to our current capital limitations. Our approach to the research and development of our product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. LTI-03 is currently in Phase 2 clinical development. It will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through clinical trials to regulatory approval. We are still in mid-stage clinical development and may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biopharmaceutical 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 efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products.

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future and do not expect to achieve or maintain profitability; Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

We have incurred significant losses since our inception and have financed our operations principally through equity financings. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2025 and 2024, we reported an operating loss of $50.6 million and $65.1 million, respectively. As of December 31, 2025, we had an accumulated deficit of $401.3 million. We have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, raising capital, acquiring and discovering development programs, securing intellectual property rights and research and development and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential product candidates. We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance the development of our lead clinical product candidate, LTI-03, through clinical development, and, if successful, later-stage clinical trials;
- advance our preclinical development programs into clinical development;
- research and develop new product candidates;
- experience delays or interruptions to clinical trials, preclinical studies, our receipt of materials and services from our third-party service providers on whom we rely, or our supply chain;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize our product candidates and any future product candidates, if approved;

- increase the amount of research and development activities to identify and develop product candidates;
- hire additional CMC, quality control, scientific and management personnel and expand our operational, financial and management systems and personnel, including personnel to support our clinical development and manufacturing efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio; and
- invest in or in-license other technologies or product candidates.

Moreover, these factors raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If existing or potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Global and macroeconomic developments can disrupt our supply chains and adversely affect our financial condition and results of operations.

We are subject to continuing risks and uncertainties in connection with legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, trade policies, including tariffs and other trade restrictions or the threat of such actions, military actions and ongoing conflicts in the Middle East, Ukraine and elsewhere, general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates and changes in, instability in financial institutions. Most of these developments and factors are outside of our control and could exist for an extended period of time. Portions of our future clinical trials may be conducted outside of the U.S. and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including due to the impact of tariff and trade policies or conflicts in the Middle East or Ukraine could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international conflicts or trade disputes could also strain our suppliers, some of which are located outside of the U.S., possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Effective internal control over financial reporting is 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 control 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. An ineffective system of internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2025 and 2024. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial

reporting such that there is a possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. We identified the following material weaknesses in internal control over financial reporting: (i) lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and (ii) lack of adequate procedures and controls to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual reporting purposes. Refer to Part II, Item 9A. "Controls and Procedures" for additional information regarding the material weaknesses.

We have implemented and are continuing to implement procedures to remediate these material weaknesses, however, we cannot assure you that these or other measures will fully remediate the material weaknesses in a timely manner or prevent future material weaknesses from occurring. For additional information regarding our remediation measures for the material weaknesses, please refer to Part II, Item 9A. "Controls and Procedures" in this Annual Report on Form 10-K.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold a portion of cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation, or FDIC, standard deposit insurance limit of $0.25 million. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short term liquidity and ability to meet our operating expense obligations.

For example, on March 10, 2023, Silicon Valley Bank, or SVB, and Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the U.S. Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

We also maintain investment accounts in which we hold our investments and, if access to the funds we use for working capital and operating expenses is impaired, we may not be able to open new operating accounts or to sell investments or transfer funds from our investment accounts to new operating accounts on a timely basis sufficient to meet our operating expense obligations.

Risks Related to the Discovery, Development and Commercialization of Product Candidates

Our business is highly dependent on the success of our lead product candidate, LTI-03.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We have our lead product candidate, LTI-03, in Phase 2 clinical development. If it encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We have completed a Phase 1a safety and tolerability clinical trial of LTI-03 in healthy normal volunteers and conducted a Phase 1b dose ranging, placebo-controlled safety and tolerability trial of LTI-03 in IPF patients. We must successfully complete Phase 3 clinical trials prior to obtaining the FDA approval of LTI-03 for commercial use.

For each product candidate, we must demonstrate its safety and efficacy in humans, obtain regulatory approval in one or more jurisdictions, obtain manufacturing supply, capacity and expertise, and substantially invest in marketing efforts before we are able to generate any revenue from such product candidate.

Before we can generate any revenue from sales of our clinical product candidate, LTI-03, we must perform additional clinical studies and/or preclinical development, and complete regulatory review and approval in one or

more jurisdictions. In addition, if one or more of our product candidates is approved, we must ensure sufficient commercial manufacturing capacity and conduct and finance significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including, but not limited to:

- negative or inconclusive results from our clinical trials or preclinical studies or the clinical trials or preclinical studies of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or to abandon a program;
- drug-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting Investigational New Drug applications, or INDs, or comparable foreign regulatory applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials or our drug development strategy;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate or delayed supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party manufacturers, contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays in obtaining any pre-market inspections required by the FDA or other regulatory agencies;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory review process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Our approach to drug research and development in the area of fibrotic diseases, with a focus on Cav1-related peptides, is unproven and may not result in marketable products.

Our approach is to develop targeted treatments for fibrosis with an initial focus on Cav1 biology and utilization of its caveolin scaffolding domain, or CSD, peptide region. However, to date, this mechanism has not been definitively proven to successfully treat fibrosis in patients. Utilizing a Cav1-related peptide to treat fibrosis is a novel approach in a rapidly developing field, and there can be no assurance that we will not experience unforeseen problems or delays in developing our product candidates, that such problems or delays will not result in unanticipated costs, or that any such development problems can be solved. Therefore, we may ultimately discover that our approach and any product candidates resulting therefrom do not possess properties required for therapeutic effectiveness. As a result, we may never succeed in developing a marketable product.

In addition, while we have utilized cell assays, precision cut lung slice models, and in vivo animal models to assess both anti-fibrotic and epithelium preservation functions of Cav1-related peptides, there can be no assurance that our technology will yield its intended benefits in human patients.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulatory authorities may require us, to conduct additional clinical trials or nonclinical studies. We will be required to demonstrate with substantial evidence through well-controlled, adequate clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities despite having progressed through nonclinical studies and early-stage clinical trials.

From time to time, we may publish or report topline, interim or preliminary data from our clinical trials. We make assumptions, estimates, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, topline, interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of such trials and are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data from the trials become available. Topline, interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, topline, interim or preliminary data should be viewed with caution until the final data are available.

We are conducting and may in the future choose to conduct clinical trials for current or future product candidates outside of the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed for development or regulatory authorization or not receiving approval for commercialization in the applicable jurisdiction.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of LTI-03.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize LTI-03, including, but not limited to:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;

- we may experience delays in reaching, or we may fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or patient recruitment and enrollment may be slow or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- 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, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- 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 to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. For example, we previously announced that we expect to investigate LTI-01 in an additional Phase 2 clinical trial. However, in June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 and until additional funds are raised. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 for an indefinite period due to our current capital limitations. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies or earlier clinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.

We completed a healthy normal volunteer Phase 1a clinical trial of our clinical product candidate LTI-03. During our LTI-03 Phase 1a clinical trial, subjects experienced mild Treatment Emergent Adverse Events, or TEAEs, such as dry cough, as well as moderate or even severe TEAEs, such as wheezing, chest tightness, or decline in the amount of air a person can force from their lungs in one second. While no subject experienced a Serious Adverse Event, or SAE, it is possible that subjects in future clinical studies could develop TEAEs such as the ones experienced in the Phase 1a clinical trial, and it is possible that such the number and/or severity of such TEAEs could result in a pause or cessation of the clinical trial. We have also completed Phase 1b and Phase 2a clinical trials of our clinical product candidate LTI-01 in LPE patients. In the Phase 2a trial, four subjects experienced TEAEs, including 1 mild, 2 moderate, and 1 severe TEAE. There were no SAEs reported. The product candidate was concluded to be generally well-tolerated across all doses in trial participants.

If significant adverse events or other side effects are observed in any of our ongoing or future clinical trials, whether or not related to our product candidates, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts altogether or may result in safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for the FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve many patients, have significant costs and can take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition of candidate therapies from failure of these candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and previous clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as new drugs and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of LTI-03. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including, but not limited to:

- clinical trials or preclinical studies may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- failure of contract manufacturers to comply with regulatory requirements;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many candidates that have performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Some of our future trials may be open label studies, where both the patient and investigator know whether a patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open label clinical trials test only the investigational product candidates and sometimes do so at different dose levels. Open label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open label clinical trials are aware when they are receiving treatment. In addition, open label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in the FDA policy during the period of product development and the FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA also requires a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support product candidate approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the ethical conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the U.S. and vice versa.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

Studies involving human tissue samples may also be subject to institutional and government human subject privacy policies that may vary by territory. We or our partners which use human tissue samples or conduct tissue and/or animal studies on our behalf, may be found to be in violation of one or more of these regulations or policies and may be subject to closure, censure or other penalties. In some cases, these penalties could materially impact the performance, availability, or validity of studies conducted by us or on our behalf. Even in the absence of violations resulting in penalties, regulatory and other authorities may refuse to authorize the conduct or to accept the results of studies for regulatory or ethical reasons.

If we encounter difficulties enrolling and retaining patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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 trial until its conclusion. The enrollment of patients depends on many factors, including, but not limited to:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials or are discontinued from trials at the recommendation of the principal investigator before completion.

For example, we are developing LTI-03 for the treatment of IPF, which is an orphan indication. In the U.S., IPF is estimated to affect approximately 100,000 people. As a result, we may encounter difficulties enrolling subjects in our clinical trials of LTI-03 due, in part, to the small size of this patient population. In addition, our clinical trials could compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, it is possible that we would conduct some of our clinical trials at the same clinical trial sites that a competitor uses, which would reduce the number of patients who are available for our clinical trials in such clinical trial site. Certain of our planned clinical trials may also involve invasive procedures such as bronchoscopy and broncho-alveolar lavage procedure, which may lead some patients to drop out of trials to avoid these follow-up procedures. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products.

If approved, our product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, or ACA, to establish an abbreviated pathway for the biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their biologics license application, or BLA, does not rely on the reference product, sponsor's data or submit the application as a biosimilar application.

We believe that any of the product candidates we develop that are approved in the U.S. as a biological product under a BLA may qualify for the 12-year period of exclusivity. However, there is a risk that the FDA may not grant exclusivity, this exclusivity could be shortened due to congressional action or otherwise undermined by a competitor, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

Although we have received U.S. and EU Orphan Drug Designation for LTI-03 for IPF and U.S. and EU Orphan Drug Designation for LTI-01 for pleural empyema, we may be unable to obtain and maintain Orphan Drug Designation for our other product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the U.S. and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a

rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the U.S. or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S.

Regulation (EC) No. 141/2000 specifies the requirements for designation as an orphan drug at the EU level. The medicinal product must be intended (i) for the treatment of a life-threatening or chronically debilitating disease affecting no more than five in 10,000 individuals in the EU, or (ii) for the treatment of a correspondingly serious condition described in the Regulation, and in both cases, without additional incentives, the marketing of the medicinal product must be unlikely to generate sufficient profit to justify the necessary investment. If one of the two alternatives applies, it is assumed that there is no other satisfactory treatment method or, if such a method exists, that the new product has a significant therapeutic benefit compared to it.

Although we have received U.S. and EU Orphan Drug Designation for LTI-03 for IPF and U.S. and EU Orphan Drug Designation for LTI-01 for pleural empyema, we have not received U.S. Orphan Drug Designation for LTI-01 for LPE, which is the first indication that we are pursuing for LTI-01. Furthermore, the designation of any of our product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant Orphan Drug Designation to product candidates of other companies that treat the same indications as our product candidates.

Generally, if a product candidate with an Orphan Drug Designation in the U.S. receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. Similar exclusivity rights apply under EU law if a product candidate with Orphan Drug Designation is authorized in the EU. Designation does not mean approval. Even if we obtain marketing authorization, the FDA may choose not to grant exclusivity. In the EU, market exclusivity only applies if the criteria for orphan drug designation still exist at the time when the marketing authorization is granted. The applicable period is seven years in the U.S. and ten years in the EU. Under EU law, the period of exclusivity may be reduced to six years if it is established, at the end of the fifth year, that the criteria for orphan drug designation are no longer met. In the U.S., orphan drug exclusivity may be revoked if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large biopharmaceutical and biotechnology companies that are currently pursuing the commercialization or development of products for the treatment of fibrosis. Companies that we are aware of that are targeting the treatment of various fibrosis indications include large companies with significant financial resources such as, but not limited to: AbbVie Inc., Boehringer Ingelheim GmbH, Bristol Myers Squibb Company, Gilead Sciences, Inc., Roche Holding AG, and Novartis AG. Many of our current or potential competitors, either alone or with their strategic partners, 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. There are currently no approved therapeutics for the treatment of LPE. Roche Holding AG manufactures tissue plasminogen activator, or tPA, and recombinant deoxyribonuclease, or DNase, which are used off-label to treat LPE patients. We are not aware of any other pharmaceutical or biotechnology companies developing drug therapies for the treatment of LPE.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing LTI-03, LTI-01 and any of our other product candidates in clinical trials, and will face an even greater risk if we commercialize any products. For example, we may be sued if any of our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- adverse effects to our results of operations and business;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaboration partners. We will need to obtain additional insurance for clinical trials as LTI-03 and LTI-01 continue clinical development and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain, on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Marketing Approval

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, or biologics license applications, or BLAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs or BLAs for our product candidates, it may require that we conduct additional clinical, nonclinical or manufacturing validation

studies and submit that data before it reconsiders our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or BLA, or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs or BLAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if a product candidate we develop 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.

Even if LTI-03 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage, and adequate reimbursement; and
- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

In addition, even if we obtain approval, the FDA or a comparable foreign regulatory authority might add specific warnings to the product label, making promotion more difficult. In the U.S., for example, a product with a "Boxed Warning" which is a call-out warning for the possibility of a serious, life-threatening risk, carries promotional restrictions. In addition, due to the nature of the serious risk potentially associated with the drug, necessitating the Boxed Warning, public acceptance of the product may be challenging.

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 collaborators, from obtaining approvals for the commercialization of LTI-03, LTI-01 or any other product candidate that we may develop. As a result, we cannot predict when or if, and in which territories or for which indications, we, or any future collaborators, will obtain marketing approval to commercialize LTI-03, LTI-01 or any other product candidate that we may develop.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drugs are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the U.S. or in other countries until we or they receive approval of an NDA or BLA from the FDA or marketing approval from comparable foreign regulatory authorities. LTI-03 is in mid-stage of development and is subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for LTI-03 in the U.S. or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including the FDA approval of an NDA or BLA.

The process of obtaining marketing approvals, both in the U.S. and abroad, is a lengthy, expensive and uncertain process. It may take many years, 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. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities have substantial discretion and may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions, such as the aforementioned Boxed Warning in the product label, or post-approval commitments that render the approved product not commercially viable.

Further, the FDA may determine that we must provide additional evidence and data before approving a BLA or NDA for our candidate products. For example, the FDA reviews an application to determine whether there is "substantial evidence" to support a finding of effectiveness for the proposed product for its intended use(s), the FDA has interpreted this evidentiary standard to generally require at least two adequate and well-controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional confirmatory evidence may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate effectiveness. In the event that we submit a BLA or NDA on the basis of one clinical trial and confirmatory evidence, the FDA could determine that such information is not sufficient to support approval of the application and the agency could require us to conduct an additional trial in support of the BLA or NDA.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any collaborators we may have to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we are granted for LTI-03 or LTI-01 in the U.S. would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell our products in the EU and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products candidates in any market.

In many countries outside the U.S., a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the U.S. or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the U.S., including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the U.S.

The design or execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. We completed a Phase 2a dose-ranging, placebo-controlled trial of LTI-01 in LPE patients. We may need to investigate higher or lower doses of LTI-01 in future clinical trials to establish efficacy and safety. Additionally, as no drug has been approved for LPE, our Phase 2a primary endpoint of treatment failure, defined as death or referral to surgery by a specific criteria checklist within seven days of commencing treatment may not be considered an appropriate endpoint for approval by the regulatory authorities. The trial results did not show statistical significance on the primary endpoint. Additionally, our highest dose of LTI-01 in this trial showed a lower effect than the other LTI-01 doses tested. Based on the results of this trial, we expect to investigate LTI-01 in a Phase 2b dose-ranging, placebo-controlled clinical trial with a lower dose to establish efficacy and safety. However, in June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 and until additional funds are raised. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 for an indefinite period. Even with additional clinical trial testing with a modified primary endpoint, we may never be successful in demonstrating sufficient results to support marketing approval.

Additionally, in some instances, there can be significant variability in safety or efficacy results between different clinical trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from clinical trials or preclinical studies. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials or a more restrictive label than we expect (e.g., Boxed Warning). Similarly, the FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

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

The FDA may not approve an ANDA for a generic drug until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA and the FDA may not approve the application until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid, will not be infringed by the generic drug, or unenforceable, in which case the applicant may submit its application four years following approval of the reference-listed drug. Manufacturers may seek to launch these generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for our drug.

Competition that our drugs may face from generic or competitor versions of our drugs could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those drug candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those drug candidates may be substantially limited if our drugs, if and when approved, are not afforded the appropriate periods of non-patent exclusivity.

Risks Related to Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates, if approved.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous

responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate, or include specific safety-related label warnings that could affect marketing efforts. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, 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. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

We may seek to obtain certain regulatory designations for our product candidates. We may not receive such designations, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek to obtain breakthrough therapy designation, fast track designation, or priority review designation for our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug 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 fast track designation is possible for drugs intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition. In addition, if the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time an NDA is submitted to the FDA.

Such regulatory designations are within the discretion of the FDA, and the FDA may not approve any application that we submit. Even if we were to obtain breakthrough designation or fast track designation, the FDA may subsequently withdraw such designation if the FDA determines that the designation no longer meets the conditions for qualification or is no longer supported by data from our clinical development program. In addition, receipt of any such designations may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA of any drug candidates so designated.

Accelerated approval by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of any of our current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for

accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA or NDA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from the FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

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 research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. 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 may also 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. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination, and as such we would have to pay the full amount of any resultant liability out of pocket, which could significantly impair our financial condition.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA, prohibits any U.S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain 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 for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to the FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

We currently rely on foreign third-party manufacturers, including those in China. The U.S. government and persons involved in the Trump administration have made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies. In February 2025, the U.S. government announced a 10% tariff on imports from China. If maintained and if extended to other countries, tariffs and the potential escalation of trade disputes with China and other countries could pose a significant risk to our business and could result in higher operating expenses. The extent and duration of any tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the United States and China and/or other countries, the response of such countries, exemptions or exclusions that may be granted, availability and cost of alternative sources of supply of materials we purchase from companies in China or other countries targeted with tariffs.

Trade tensions and conflicts between the U.S. and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the U.S. or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material or services to us. In 2024, the U.S. House of Representatives passed the BIOSECURE Act, and the Senate has advanced a substantially similar bill. Though such legislation was not enacted into law in 2024, Congress could re-introduce similar measures, which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern", without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties could be impacted by such legislation.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

In addition to our operations in the U.S., we may seek to conduct clinical trials in the EEA and may become subject to additional European data protection laws, regulations and guidelines. The GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the U.S., providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent to certain processing activities from the individuals to whom the personal data relates, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR provides for substantial penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to two percent of our total worldwide annual revenues, whichever is greater, for certain comparatively minor offenses, or up to 20,000,000 Euros or up to four percent of our total worldwide annual revenues, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers, and recent court decisions and regulatory guidance have substantially increased the compliance burden and legal uncertainty associated with transferring the personal data of EEA individuals to third countries outside of the EEA whose data protection laws are not believed to be adequate by European standards (although the recent EU-US Data Privacy Framework offers a new route for data transfers from the EU to be made lawfully to the U.S.).

Further, the GDPR provides for opening clauses in certain areas, which enable the legislators of member states of the EU to implement additional requirements to the GDPR in national law, whereby national laws may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA.

Also, as it relates to processing and transfer of genetic, biometric and health data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The UK's decision to leave the EU (and it is important to note that the EEA does not include the UK), often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK and to what extent UK law will diverge from the GDPR in the future. At this point in time, the UK Government has incorporated the GDPR into UK law, known as the "UK GDPR", but has also published proposals recently to reform UK data protection law which are going through the UK Parliament and likely to become law in 2024. In the context of international data transfers, European Commission has issued adequacy decisions which have the effect of authorizing data transfers from the EEA to the UK. The UK Government and the Information Commissioner's Office have also published proposals recently to indicate how data transfers between the UK and the rest of the world will be regulated now that the UK has left the EU. For instance, the UK Government proposes recognizing more countries as adequate for data transfers as part of reducing barriers to data flows—this would include countries not yet authorized by the European Commission. The UK Government has also approved the UK Extension to the EU-US Data Privacy Framework for data transfers from the UK to the U.S.

The GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is

a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We face uncertainty as to whether our efforts to comply with our obligations under European data protection laws are sufficient, and personal data transfers from the EEA to the U.S. (which include accessing in the U.S. personal data from EEA individuals, even if the data actually remains stored in the EEA) may face particular scrutiny. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or biopharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, 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. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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 new product candidates to be reviewed and/or approved by necessary government agencies, which would 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 FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our 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.

The same is true of disruptions related to public health emergencies that have occurred or that may occur in the future. For example, during the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. The FDA has now indicated that it can and will conduct timely reviews of applications for medical products in line with its user fee performance goals, including conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, in the event of a resurgence of the COVID-19 pandemic or another similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to future emergencies and may also experience delays in their regulatory activities.

The application of newly developed artificial intelligence and other technologies which are widely anticipated to reduce the development time to bring new products to market may materially increase the volume of applications for product approval to the FDA compared to historical application levels. If this increased application volume materializes and additional staff and resources are not allocated to the FDA, the FDA may not be able to continue its current pace of application reviews and review timelines could be extended. Regulatory authorities outside the U.S. facing similar increases in application volume may also experience delays in their regulatory activities. Accordingly, if a prolonged government shutdown or other disruption occurs, or the volume of application to the FDA for new product candidates increases materially, 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. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Further, with the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. There is also uncertainty as to how other measures being implemented by the Trump Administration across the government will our activities and those of the FDA and its operations. For example, the potential loss of the FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new administration to substantially reduce research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend upon third parties to conduct certain aspects of our clinical trials and preclinical studies, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP or other requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional clinical trials or preclinical studies

before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our clinical trials or preclinical studies will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs and preclinical studies. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if due to federal or state orders they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for clinical trials and preclinical studies. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices.

The manufacturing process for a product candidate is subject to the FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fail to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all, or on a delayed basis. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or may require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within

budget. In addition, the new manufacturer must comply with the aforementioned quality-related regulatory requirements.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for LTI-03. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure to execute on our manufacturing requirements and comply with cGMP or other requirements could adversely affect our business in a number of ways, including, but not limited to:

- an inability to initiate or continue clinical trials of product candidates under development;
- imposition of a clinical hold;
- initiation of an Import Alert or Automatic Detection;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates;
- increase manufacturing costs for delays and/or finding replacement manufacturers; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP and other regulatory compliance can result in a contractor receiving sanctions by the FDA or another foreign regulatory agency, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractors are operating in accordance with cGMP and other regulatory requirements, but we can give no assurance that the FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business.

We depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture of our product candidates for clinical trials, and the loss of these third-party suppliers and manufacturers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing our product candidates requires many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. If this sole supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long-term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event that any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer.

In addition, we developed the cell line and manufacturing process for drug substance manufacture in collaboration with our sole manufacturer. The loss of this contract development and manufacturing company, or

CDMO, or its failure to supply us with material to support our clinical development program on a timely basis could impair our ability to develop our product candidates or otherwise delay the development process, which could adversely affect our business, financial condition and results of operations. Some of our CDMO's raw material suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP or other regulatory requirements by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers directly, and we or our CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we or our CDMOs may experience delays in receiving key raw materials and equipment to support clinical or commercial manufacturing.

For some of these specialty materials, we and our CDMOs rely on and may in the future rely on sole-source vendors or a limited number of vendors. The supply of specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for clinical or commercial production, applicable regulatory agencies may inspect the new vendor or require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct preclinical and clinical trials, either of which could significantly harm our business.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting 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. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent

applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for U.S. applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the U.S. moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Intellectual property rights do not necessarily address all potential threats to our business. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;

- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the U.S.;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations, and prospects.

We are currently party to license or other collaboration agreements that impose certain obligations on us, and we may enter into additional license or collaboration agreements in the future. If we fail to comply with our obligations under such present or future agreements with third parties, we could lose license rights that may be important to our business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Our existing licensing agreements with UTHSCT, the University of Texas at Austin, the Medical University of South Carolina, and Vivarta Therapeutics, LLC contain diligence obligations to maintain each license agreement.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, our limited control over the prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property may allow the licensors to pursue additional patent applications with limited input from us. Result in the licensor to pursue filing and prosecuting patent applications or obtaining patents without our knowledge or agreement. Such conduct by the licensor could have a material adverse effect on our business. We cannot also be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed.

If we collaborate with third parties for the development or commercialization of our current or future product candidates, we must, at times, share proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our employees, collaborators, advisors, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information becomes known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, a competitor's discovery of our know-how or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our employees, collaborators, advisors, third-party contractors, and consultants to publish data potentially relating to our know-how. Despite our efforts to protect our

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

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

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming.

In addition, in an infringement proceeding, a court may decide that one or more of our patents 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 or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the U.S. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time, and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors,

misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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. In addition, there could 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 a substantial adverse effect on the price of our common stock.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or

proprietary technologies infringe their intellectual property rights. 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 our product candidates, and further applications in the fields could continue to be filed. For example, even if we were the first to file a patent application related to our technology, we cannot be certain that a third-party is or will be filing and prosecuting patent applications related to our technology or related to our field, which could have a material adverse effect on our business.

As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. There can be no assurance that our business does not, or will not in the future, infringe, misappropriate, or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our business is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the U.S. and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. 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 candidates, or the use of our product candidates. 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 candidates or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidates.

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. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our product candidates, their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive. Competitors may use our technology in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by us to enforce our patent rights or by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we become party to and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and 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 foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of

a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of samples or other materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do not cover intellectual property rights. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

In addition, we may in the future be subject to claims by former employees, collaborators, or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding 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 technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidates 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 technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, 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 our or our licensors' ownership of our patents, trade secrets or other intellectual property. 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, intellectual property that is important to our product candidates. 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 of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, infringing, misappropriating, or otherwise violating their intellectual property rights. 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.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates,

intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize 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 claim of infringement 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 infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Any current or future patents, if issued, covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity

question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

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

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On March 16, 2013, under America Invents Act, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or 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 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 new court system,

there is no precedent for the court, increasing the uncertainty of any litigation. 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 pan-European injunction. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. We cannot predict how future decisions by the courts, the United States Congress, or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, and results of operations.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims 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, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions 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 issuing 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. 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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive 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.

The U.S. patent licensed from the Board of Regents of the University of Texas System directed to methods of using intrapleural single chain urokinase plasminogen activator, or scuPA, polypeptide for decreasing the severity of

pleural scarring, expired in 2024 without patent term extension. We cannot assure that, we will not face competition from competitive products, now that the patent has expired. We plan to rely on the 12 years of data exclusivity provided under the BPCIA, as well as the complexity of the manufacturing process of LTI-01. There can be no assurance that BPCIA product protection will be available if LTI-01 is approved, or the Company will be able to maintain the confidentiality of its trade secrets and know-how in its manufacturing process.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, obtain approval of competing products, and launch their products earlier than might otherwise be the case, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

Any name we propose to use with our product candidates in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

Risks Related to Employee Matters and Managing Growth

Our internal computer systems, or those of our vendors or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Although we attempt to secure our systems and have a process to identify and mitigate threats, our internal computer systems and those of our current and any future vendors and other contractors or consultants are vulnerable

to damage from computer viruses, ransomware attacks and other malicious behavior, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, attack or security breach to date, if such an event were to occur and cause interruptions in our operations, it 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, inability to access critical systems and applications, or other similar disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption, attack or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur costs of notification to individuals, regulators and other third parties, remediation costs, liability to our customers or third parties and/or regulatory fines and penalties, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, ransomware and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to respond to an incident and repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, failure to use reasonable measures to safeguard data, violation of state laws protecting the confidentiality, privacy and integrity of personal information and health-related information, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our own technology and information systems and manage potential security risks associated with our vendors. In addition, there can be no assurance that our internal information technology systems or those of our third-party vendors, or our and our vendors' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted or the company being subject to attempted extortion in the event of a cyberattack or ransomware attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Risks Related to Our Common Stock

If we fail to maintain compliance with the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. We are required to meet specified requirements to maintain our listing on the Nasdaq Capital Market, including a minimum bid price of $1.00 per share for our common stock and standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. In the past we have, from time to time, received written notification from the Nasdaq Stock Market informing us that we were not in compliance with certain continued listing requirements of the Nasdaq Capital Market. There can be no assurance that we will continue to maintain compliance with the requirements for listing our common stock on the Nasdaq Capital Market. Any potential delisting of our common stock from the Nasdaq Capital Market would likely result in decreased liquidity and increased volatility for

our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our common stock from the Nasdaq Capital Market would also make it more difficult for our stockholders to sell our common stock in the public market.

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

Our shares of common stock began trading on The Nasdaq Global Market on June 29, 2017, and transferred to The Nasdaq Capital Market, effective December 30, 2019. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of stockholders to sell their shares. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If few analysts commence, or if analysts discontinue, coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

The trading price of our common stock is 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. These factors include:

- the timing and results of clinical trials of LTI-03;
- our ability to raise additional capital as and when needed;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for LTI-03 and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of LTI-03;
- changes in laws or regulations applicable to LTI-03, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of LTI-03;
- introduction of new products or services offered by us or our competitors;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in our quarterly operating results or those of companies that are perceived to be similar to us;
- our cash position;
- our failure to meet, or actual or anticipated changes in, the estimates and projections as to financial results, development timelines or recommendations of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions;
- the level of expenses related to our product candidates or clinical development programs;
- investors' general perception of us and our business; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for 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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We could be subject to securities class action litigation.

Our stock price has been and will likely continue to be volatile. In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. The TCJA, as amended by the CARES Act, significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and, the limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). In addition, beginning in 2022, the TCJA eliminated the option to deduct research and development expenditures currently and requires corporations to capitalize and amortize them over five years or fifteen years (for expenditures attributable to foreign research).

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The Inflation Reduction Act, or IRA, was also signed into law in August 2022. The IRA introduced new tax provisions, including a 1% excise tax imposed on certain stock repurchases by publicly traded corporations. The 1% excise tax generally applies to any acquisition by the publicly traded corporation (or certain of its affiliates) of stock of the publicly traded corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted. The OBBBA amends U.S. tax law including provisions related to domestic research and development expenses and bonus depreciation, among others. The provision related to domestic research and development expenses allows for immediate expensing of domestic research and development costs along with accelerated deductions on previously capitalized domestic research and development costs. The Company has included impacts for the provisions in effect for tax years beginning after December 31, 2024 in its consolidated financial statements for the year ended December 31, 2025 and notes there was not a material impact.

Regulatory guidance under the OBBBA, TCJA, the IRA, and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the OBBBA, TCJA, the IRA, and additional tax legislation.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

A significant portion of our total outstanding shares may be sold into the market at any time, 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. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 24, 2026, we had 28,039,032 shares of common stock outstanding and 12,232 shares of our Series X non-voting convertible preferred stock, or Series X Preferred Stock, outstanding, which were convertible into 12,232,000 shares of common stock, subject to beneficial ownership limitations.

In connection with our October 2023 private placement, we filed a resale registration statement with the SEC covering the resale of the shares purchased by the purchasers in the private placement and shares issuable upon exercise of the warrants issued in the private placement. The shares subject to the resale registration statement no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any purchaser and subject to volume limitations applicable to affiliates.

We have also registered all shares of common stock that we may issue under our equity compensation plans, including upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Assuming the conversion of all outstanding Series X Preferred Stock and the exercise of outstanding warrants, there is a concentration of ownership of our outstanding common stock by one group of affiliated stockholders. If this group chooses to act together, it could exert substantial influence over our business, and the interests of this group may conflict with those of other stockholders.

As of March 24, 2026, entities and individuals affiliated with Bios Partners, or collectively, the Bios Entities, beneficially owned 7.11% of our outstanding common stock. This ownership percentage does not, due to certain restrictions on conversion and exercisability, take into account the issuance of all shares of our common stock upon conversion of the Series X Preferred Stock or upon exercise of the warrants issued to the Bios Entities in our October 2023 private placement.

The Certificate of Designation for the Series X Preferred Stock provides that any holder of Series X Preferred Stock will not have a right to convert, subject to certain exceptions, the Series X Preferred Stock for our common stock if, as a result of such conversion, the holder, together with its affiliates and other attribution parties, would hold 19.99% of the total number of shares of our common stock then outstanding, subject to decrease upon written notice by the holder. Similarly, under the terms of the warrants a holder shall not have the right to exercise any portion of any warrant, to the extent that after giving effect to such exercise, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates), would beneficially own in excess of a percentage elected by the holder up to 19.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the warrants. Assuming the conversion of all outstanding Series X Preferred Stock and the exercise of all outstanding warrants, options and any other rights to acquire our common stock, and without giving effect to the foregoing beneficial ownership limitations on Series X Preferred Stock and the warrants, the Bios Entities would, as of March 24, 2026, own 38.4% of our common stock on a fully diluted basis.

If any of the Bios Entities acted together, they could be able to exert substantial influence over our business. Additionally, the interests of the Bios Entities may be different from or conflict with the interests of our other stockholders. This concentration of voting power with the Bios Entities could delay, defer, or prevent a change of control, entrench our management and the Board of Directors, or delay or prevent a merger, consolidation, takeover, or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and the Bios Entities on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for shares of common stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will 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 any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. We do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We are a clinical stage biopharmaceutical company with no commercial operations or revenue streams and our sole business activity has been ongoing research into our drug therapies. We have certain processes for assessing, identifying and managing cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems, which are built into our overall risk management program. Our processes are designed to preserve the confidentiality, integrity, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur. Such processes include physical, procedural and technical safeguards, and response plans on our systems. We engage an external consultant to manage cybersecurity tooling and incident response, as well as general information technology, or IT, systems, which enhance our cybersecurity oversight. We consider the internal risk of oversight programs of the third-party consultant before engaging them in order to help protect us from any related

vulnerabilities. As our company grows, we plan to expand our strategy for cybersecurity in alignment with nationally accepted standards.

Based on an assessment using the previously described cybersecurity risk management program, we do not believe that there are currently any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For additional information regarding risks from cybersecurity threats, please refer to Item 1A. "Risk Factors" in this Annual Report on Form 10-K.

Governance

Our management and board of directors recognize the critical importance of maintaining the trust and confidence of our business partners and employees, including the importance of managing cybersecurity risks as part of our larger risk management program. We seek to address cybersecurity risks through a cross-functional approach.

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our audit committee, comprised of members with substantial experience in information technology governance and risk management, oversees our cybersecurity strategy. Our board of directors receives periodic updates from management regarding cybersecurity matters, and is notified between such updates regarding significant new cybersecurity threats or incidents.

Our executive officers are responsible for the day-to-day management of the material risks that we face. Our executive officers are led by a third-party consultant, who oversees company-wide cybersecurity strategy, policy, standards and processes and works across relevant departments to assess and help prepare us and our employees to address cybersecurity risks. The third-party consultant is advised by their Security Operations Center Manager with a variety of technical certifications, as well as extensive background in IT infrastructure, risk mitigation, and incident response planning.

In an effort to deter and detect cyber threats, we annually provide all employees, including part-time and temporary employees, with a data protection, cybersecurity and incident response and prevention training and compliance program, which covers a range of timely and relevant topics. Past topics have included social engineering, phishing, password protection, confidential data protection, asset use and mobile security. The training and compliance program functions to educate employees on the importance of reporting all incidents immediately. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

Item 2. Properties

On August 16, 2021, Lung entered into an operating lease agreement to rent approximately 6,455 square feet of office space for its corporate headquarters in Austin, Texas, beginning on October 1, 2021. The lease expired March 31, 2024, and we did not renew the lease. Following expiration of the lease, we are operating virtually, and expect to do so for the foreseeable future. Our current address is used solely as a mailing address for the receipt of correspondence.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse impact on us because of defense and settlement, costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock trades under the symbol "RNTX" on the Nasdaq Capital Market and had been publicly traded since June 29, 2017. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of March 24, 2026, there were approximately 117 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividend Policy

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future. Any future determination to pay cash dividends will be made at the discretion of our board of directors and will depend on restrictions and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Securities

In April 2025, certain institutional investors, including Bios Equity Partners, LP, or Bios Partners, exercised warrants for the purchase of 1,049,638 share of our common stock for the gross proceeds of $1.7 million and exchanged outstanding warrants for pre-funded warrants and the cash purchase price of an aggregate of $3.1 million. All shares of common stock and warrants were issued pursuant to Section 4(a)(2) of the Securities Act, as transactions not involving a public offering. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations–Overview and Recent Developments–April 2025 Warrant Transactions and Private Placement."

During the year ended December 31, 2025, we sold 2,727,162 shares of our common stock to Yorkville, in satisfaction of an aggregate of $3.0 million of principal and accrued interest owed by us to Yorkville under our Pre-Paid Advance Agreement dated July 29, 2025. All shares of common stock issued and sold to Yorkville were issued pursuant to Section 4(a)(2) of the Securities Act, as transactions not involving a public offering.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Equity Compensation Plan Information

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis are meant to provide material information relevant to an assessment of the financial condition and results of operations of our Company, including an evaluation of the amounts and certainty of cash flows from operations and from outside sources, so as to allow investors to better view our Company from management's perspective. You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" in this Annual Report on Form 10-K.

Overview and Recent Developments

We are a clinical stage biopharmaceutical company focused on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. We currently have one lead product candidate in clinical development, LTI-03. As a result of our current capital limitations, we have suspended development activities for LTI-01 and our candidates in preclinical development focused on fibrosis indications for an indefinite period and are allocating our limited resources to LTI-03, as it is further discussed below. Our pipeline includes:

- LTI-03, a peptide, for which we conducted a Phase 1b dose-ranging, placebo-controlled safety, tolerability, and pharmacodynamic biomarker activity trial in development for the treatment of Idiopathic Pulmonary Fibrosis, or IPF, that has demonstrated the ability to protect healthy lung epithelial cells and reduce pro-fibrotic signaling;
- LTI-01, a proenzyme that completed a Phase 2a dose-ranging, placebo-controlled trial and a Phase 1b safety, tolerability and proof of mechanism trial in loculated pleural effusion, or LPE, patients, an indication that has no approved drug treatment; and
- preclinical programs targeting cystic fibrosis and a peptide program focused on the Cav1 protein for systemic fibrosis indications.

In June 2024, we decided to temporarily delay clinical development of LTI-01 and other pre-clinical candidates in an effort to focus our resources on clinical development of LTI-03 and until additional funds are raised. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 for an indefinite period.

In May 2025, we initiated screening and recruitment of patients in the RENEW Phase 2 clinical trial of LTI-03. The RENEW trial is a Phase 2 multi-center, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, and efficacy of LTI-03 patients with IPF. In addition, the trial is designed to assess the activity of inhaled dry powder LTI-03 across multiple biomarkers and to measure lung function and the potential for healthy tissue regeneration. The trial is designed to enroll approximately 120 patients diagnosed with IPF within 5 years of screening, who may be receiving standard of care antifibrotic therapy, across up to 50 sites globally, including sites in the United States, United Kingdom, Germany, Austria and Poland. Patients will be randomized into two blinded placebo-controlled cohorts that will run concurrently. Patients in the low dose cohort will receive 2.5 mg of either LTI-03 or placebo administered twice daily, or BID, for a total dose of 5 mg/day, while participants in the high dose cohort will receive 5 mg BID for a total dose of 10 mg/day. The primary endpoint is the incidence of treatment-emergent adverse events from Day 1 through Week 24. The key secondary endpoint is the efficacy of LTI-03 measured through forced vital capacity, percent predicted FVC and high-resolution computer tomography, in collaboration with Qureight Ltd. Patients will undergo a 28-day screening period prior to being randomized and entering the 24-week treatment period, with a four-week follow-up.

In October 2025, we received authorization from the European Medicines Agency, or the EMA, to initiate our Phase 2 RENEW trial of our lead candidate, LTI-03, at sites in Germany and Poland. We had previously received regulatory clearance from the U.K.'s Medicines and Healthcare products Regulatory Agency, or the MHRA. In January 2026, we received orphan drug designation from the EMA for LTI-03.

As of the date of this Annual Report, we activated sites and are enrolling patients in the U.S. and are seeking to activate additional sites, enroll patients and initiate the RENEW trial throughout the U.S., UK, Europe and other jurisdictions. In March 2026, we dosed our first patient in the RENEW Phase 2 clinical trial of LTI-03. We expect to report initial interim topline data on some proportion of patients in the fourth quarter of 2026.

We have not completed the development of any of our product candidates, have not generated any revenue from product sales and have never generated an operating profit.

To date, we have financed operations primarily through $145.5 million in net proceeds from sales of common stock and warrants, $2.2 million in net proceeds from sales of common stock under our "at the market" offering program, $131.2 million from sales of preferred stock prior to our initial public offering, or IPO, $34.9 million from a collaboration agreement in 2010, $17.5 million in net proceeds in connection with a private placement following the Lung Acquisition (as defined below) in 2023, $17.7 million in net proceeds in connection with the issuance and sale of shares and accompanying warrants in our public offering in May 2024, $5.1 million in net proceeds from the April 2025 Transactions (as defined below), $2.9 million in net proceeds from the Yorkville Transactions described below and $4.3 million of net proceeds from our 2026 promissory notes described below. As of December 31, 2025, we had $3.2 million in cash and cash equivalents, without giving effect to the $4.3 million of proceeds from our 2026 promissory notes.

Since our inception, we have incurred significant losses on an aggregate basis. Our net losses were $49.9 million and $62.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $401.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment and general and administrative costs associated with our operations as well as the impairment loss on intangible assets. We expect to continue to incur operating losses for the foreseeable future.

As of December 31, 2025, we had cash and cash equivalents of $3.2 million. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2025, together with the $4.3 million of proceeds received by us pursuant to the securities purchase agreements we entered into in January and February 2026, will be sufficient to enable us to fund our planned operating expense and capital expenditure requirements into the second quarter of 2026. These funds are not sufficient to enable us to complete the Phase 2 RENEW clinical trial of LTI-03 and we will need to obtain additional funding prior to completing the trial. Our future viability is dependent on our ability to raise additional capital to finance our operations. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. In addition, our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, or at all. If we are unable to obtain sufficient funding on terms acceptable to us, on a timely basis or at all, we may be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

2026 Bridge Loans

In January 2026 and February 2026, we entered into separate securities purchase agreements, or the Purchase Agreements, with three institutional investors pursuant to which we issued and sold to the investors, in a private placement, unsecured promissory notes in the aggregate original principal amount of $5.4 million, or the Notes. Pursuant to the Purchase Agreements, we issued and sold the Notes to the investors for the aggregate purchase price of $4.3 million, inclusive of an original issue discount of 20%.

The Notes have a stated maturity date of the earlier of (i) the date of the closing of the next issuance and sale of our securities, in a single transaction or series of related transactions, to investors resulting in gross proceeds to us of at least $10.0 million (exclusive of the Notes proceeds) or (ii) June 30, 2026. Our obligations under the Notes are unsecured. There is no interest payable under the Notes other than the 20% original issue discount. The Purchase Agreements contained representations, warranties, covenants and other terms customary for agreements of such nature.

Pre-Paid Advance Agreement and Standby Equity Purchase Agreement with Yorkville

On July 29, 2025, we entered into a Pre-Paid Advance Agreement, or the PPA, and a Standby Equity Purchase Agreement, or the SEPA, with YA II PN, Ltd., a Cayman Islands exempt limited partnership, or Yorkville. The PPA and the SEPA are collectively referred to as the Yorkville Transactions.

Under the PPA, we may request up to $6.0 million in pre-paid advances from Yorkville over a 12-month period, subject to certain limitations and conditions set forth in the PPA. Each pre-paid advance will be purchased by Yorkville at 95% of the face amount of the pre-paid advance. An initial pre-paid advance of $1.0 million was purchased on July 29, 2025 by Yorkville, for net proceeds of $0.95 million. Each additional pre-paid advance shall be subject to the consent of Yorkville. Interest shall accrue on the outstanding balance of any pre-paid advance at an annual rate of 8%, subject to an increase to 18% upon events of default described in the PPA. At any time that there is an outstanding balance under any pre-paid advances, Yorkville may provide a written notice to require us to issue and sell shares of common stock to offset against and reduce the balance under the pre-paid advances at a price per share equal to the lower of (i) 115% of the daily volume weighted average price, or the VWAP, of our common stock on the Nasdaq Capital Market on the last full trading day immediately prior to the date of such pre-paid advance and (ii) 95% of the lowest daily VWAP on the Nasdaq Capital Market during the seven consecutive trading days immediately preceding the date on which Yorkville provides such a purchase notice, subject to a floor price of $0.28 per share. Cash amortization payments will be triggered if the daily VWAP falls below the floor price for five of seven consecutive trading days, or in the event of any shares issued pursuant to the PPA are not eligible to be sold pursuant to an effective registration statement for a period of 10 consecutive trading days, or if we have issued substantially all of the shares available under certain exchange cap limitations.

On September 8, 2025, Yorkville purchased a second Pre-Paid Advance, or the Second Advance, of $1.0 million, for which we received net proceeds of $0.95 million. On October 23, 2025, Yorkville purchased a third Pre-Paid Advance, or the Third Advance, of $1.0 million, for which we received net proceeds of $0.95 million. As of the date of this report, we have issued 953,765 shares of our common stock, at a weighted average price per share of approximately $1.056, to Yorkville, which were offset against $1.0 million of the outstanding principal and accrued interest under the initial Pre-Paid Advance, and issued 927,107 shares of our common stock, at a weighted average price per share of approximately $1.082, to Yorkville, which were offset against $1.0 million of the outstanding principal and accrued interest under the Second Pre-Paid Advance, and issued 846,290 shares of our common stock, at a weighted average price per share of approximately $1.183, to Yorkville, which were offset against $1.0 million of the outstanding principal and accrued interest under the Third Pre-Paid Advance. All three Pre-Paid Advances were fully settled as of December 31, 2025, with no remaining outstanding balance. Accordingly, the fair value of the liabilities at December 31, 2025, was $0, and no adjustment for changes in fair value was required during the year ended December 31, 2025.

Separately, under the SEPA, we may sell up to $15.0 million of our common stock to Yorkville over a 36-month period at our discretion. Sales under the SEPA are based on our advance notices and may be for a number of shares up to 100% of the average daily trading volume of our common stock during the five trading days immediately prior to the date of each such notice, priced at 96% of the lowest daily VWAP of our common stock on the Nasdaq Capital Market during the three consecutive trading days commencing on the date of delivery each notice, subject to a minimum price floor set by us. As consideration for Yorkville's commitment to purchase our common stock under the SEPA, we agreed to pay to Yorkville a commitment fee of $0.3 million, which was satisfied by the issuance to Yorkville of an aggregate of 213,099 shares of our common stock. We did not issue shares of our common stock to Yorkville under the SEPA.

The issuance of shares under both the PPA and SEPA was subject to a cap equal to 19.9% of our outstanding common stock as of July 29, 2025, unless stockholder approval is obtained or other specified conditions are met.

On December 11, 2025, we terminated the PPA and SEPA.

Advisory Agreements

We have entered into various arrangements with certain business advisors, consultants, and investment institutions to assist us with fundraising and to provide certain advisory services. In connection with these arrangements, we may be required to pay such business advisors, consultants, and investment institutions certain contingent fees related to their services to the extent that certain conditions are met, such as a successful fundraising. There are no contingent fees payable under these arrangements as of December 31, 2025.

Sales Agreement with H.C. Wainwright

On May 15, 2025, we entered into an "at the market offering" agreement, or the Wainwright Sales Agreement, with H.C. Wainwright & Co., LLC, or H.C. Wainwright, as agent and/or principal, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $13.7 million from time to time through or to H.C. Wainwright by any method permitted that is deemed to be an "at the market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of December 31, 2025, we had issued and sold 999,967 shares of common stock pursuant to the Wainwright Sales Agreement for a net proceeds of $1.5 million.. In July 2025, in connection with the Yorkville Transactions, we reduced the aggregate offering price of the shares of common stock that could be offered and sold under the Wainwright Sales Agreement to $8.1 million.

Prior to entering into the Wainwright Sales Agreement, in May 2025, we terminated the equity distribution agreement, dated July 26, 2024, or the Equity Distribution Agreement, with Citizens JMP Securities, LLC, or Citizens JMP, as agent and/or principal, under which we could offer and sell up to $50.0 million of shares of our common stock from time to time through or to Citizens JMP by any method that was deemed to be an "at the market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. Through May 2025, we issued and sold 317,772 shares of common stock pursuant to the Equity Distribution Agreement for total net proceeds of $0.7 million. We did not issue or sell any other shares of common stock pursuant to the Equity Distribution Agreement in 2025.

April 2025 Warrant Transactions and Private Placement

On April 21, 2025, we entered into privately negotiated letter agreements with certain holders of the PIPE Warrants (as defined below) and certain holders of the Offering Warrants (as defined below). Pursuant to these letter agreements, these holders agreed to exercise for cash the PIPE Warrants for the purchase of an aggregate of 159,500 shares of common stock and the Offering Warrants for the purchase of an aggregate of 890,138 shares of common stock at a reduced exercise price of $1.60 per share, or the Warrant Exercises. The total net proceeds for the Warrant Exercises were $1.6 million.

On April 21, 2025, we entered into privately negotiated letter agreements with additional holders of the PIPE Warrants pursuant to which such holders surrendered PIPE Warrants exercisable for an aggregate of 1,939,000 shares of common stock for cancellation in exchange for pre-funded warrants (the "Exchange Pre-Funded Warrants") to purchase the same number of shares at an exercise price of $0.001 per share (the "Warrant Exchanges"). In connection with these exchanges, the holders also made an aggregate cash payment of $1.599 per underlying share. The total net proceeds for the Warrant Exchanges were $3.0 million. In the Warrant Exchanges, entities affiliated with Bios Equity Partners, LP, or Bios Partners, surrendered the PIPE Warrants to purchase an aggregate of 1,300,500 shares common stock plus provided the associated cash consideration of $2.1 million for Exchange Pre-Funded Warrants.

In addition, on April 21, 2025, an entity affiliated with Bios Partners, or the Bios Purchaser, purchased additional pre-funded warrants to purchase 312,695 shares of the common stock in a private placement, or the Placement Pre-Funded Warrants, pursuant to a subscription agreement at a price of $1.599 per share underlying the Placement Pre-Funded Warrants, or the Private Placement. The Private Placement closed on April 24, 2025. The total net proceeds for the Private Placement were $0.5 million. We refer to the Warrant Exercises, the Warrant Exchanges and the Private Placement as the April 2025 Transactions.

Master Services Agreement

In April 2025, we entered into a master services agreement with a third party Contract Research Organization, or CRO, under which the CRO has agreed to perform certain services in accordance with written work orders. The work orders set forth the obligations of the parties with regard to conducting the clinical research study entitled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2, Safety, Tolerability and Efficacy Study of Caveolin1-Scaffolding-Protein-Derived Peptide (LTI-03) in Patients with IPF", under our Protocol LTI-03-2001. Pursuant to the agreement, we had contracted for up to $17.0 million of master services. In August 2025, this master services agreement was terminated with no future commitment for the Company.

In December 2025, we entered into a project addendum with a third party CRO for the purposes of setting forth the responsibilities and obligations of the parties in regards to conducting a certain clinical research program entitled "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability and Efficacy of

Caveolin-1-Scaffolding-Protein-Derived Peptide in Patients with IPF" under our Protocol LTI-03-2001. Pursuant to the project addendum, we had contracted for up to $19.8 million of master services.

Follow-on public offering

In May 2024, we completed an underwritten follow-on public offering, or the Offering, pursuant to which we issued and sold 4,273,505 shares of our common stock, or the Offering Shares, and accompanying warrants, or the Offering Warrants, to purchase 4,273,505 shares of common stock, or the Offering Warrant Shares. We sold all of the Offering Shares and Offering Warrants. Each Offering Share was offered and sold together with an accompanying Offering Warrant at a combined public offering price of $4.68, and the underwriter purchased each Offering Share with an accompanying Offering Warrant at a combined price, after underwriting discounts, of $4.35. Net proceeds from the Offering were $17.7 million, after deducting underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the Offering Warrants. As of December 31, 2025, Offering Warrants to purchase 3,388,707 shares of common stock remained outstanding.

Components of Rein's Results of Operations

Revenue

We have not generated any revenue from product sales and we do not expect to generate any revenue from the sale of products in the foreseeable future.

Operating Expenses

Our expenses since inception have consisted solely of research and development costs, general and administrative, and restructuring costs.

Research and Development Expenses

For the periods presented in this Annual Report on Form 10-K, research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred in connection with the clinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing product candidates for use in our clinical trials and preclinical studies, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- expenses incurred in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and payments made under sponsored research arrangements with third parties;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- third-party license fees;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which included direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors and our clinical investigative sites.

Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

In addition, we typically use our employee and infrastructure resources across our development programs. We track outsourced development costs and milestone payments made under our licensing arrangements by product candidate or development program, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. The duration, costs and timing of clinical trials and development of a product candidate will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of the product candidates that we are developing and other research and development activities that we have conducted;
- uncertainties in clinical trial design and patient enrollment rates;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipated would be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance and corporate and administrative functions. General and administrative expenses are comprised of professional fees associated with being a public company including costs of accounting, auditing, legal, regulatory, tax and consulting services associated with maintaining compliance with exchange listing and the SEC requirements, director and officer insurance costs; and both public and investor relations costs. General and administrative expenses also include legal fees relating to patent and corporate matters; legal and other professional fees relating to our strategic process; other insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Impairment Loss on Intangible Assets

Impairment loss on intangible assets was identified in the fourth quarter of 2025 and 2024 when the carrying value of LTI-01 and other intangible assets which are early-stage programs exceeded their fair value as of December 31, 2025 and 2024, respectively.

Other Income, net

Interest and Other Income

Interest income consists of interest income earned on our cash and cash equivalents. Historically, our interest income had not been significant due to low investment balances and low interest earned on those balances. We anticipate that our interest income will fluctuate in the future in response to our cash and cash equivalents and the interest rate environment.

Other income, net consists of the income recognized under the Option Agreement with Advancium, gains or losses recognized from non-routine items such as accretion on short-term investments, and gains or losses recognized

from foreign currency transactions, original issue discount, or OID, related to the PPA, the promissory notes, and the disposal of fixed assets.

We anticipate that our interest income and investment accretion will fluctuate in the future in response to our then-current cash and cash equivalents, and then-current interest rates.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following tables summarize our results of operations for the years ended December 31, 2025 and 2024 in thousands:

	Year Ended December 31,		Increase
	2025	2024	(Decrease)
Operating expenses:			
Research and development	11,029	14,248	(3,219)
General and administrative	10,902	13,864	(2,962)
Impairment loss on intangible assets	28,700	37,000	(8,300)
Total operating expenses	50,631	65,112	(14,481)
Loss from operations	(50,631)	(65,112)	14,481
Other income, net	48	685	(637)
Income tax benefit	712	1,544	(832)
Net loss	$ (49,871)	$ (62,883)	$ 13,012

Research and Development Expenses

	Year Ended December 31,		Increase
	2025	2024	(Decrease)
Direct research and development services	$ 8,792	$ 11,967	$ (3,175)
Employee related expenses	2,119	2,200	(81)
Professional fees for services	44	34	10
Facilities and other expenses	74	47	27
Total research and development expenses	$ 11,029	$ 14,248	$ (3,219)

Research and development expenses for the year ended December 31, 2025 were $11.0 million, compared to $14.2 million for the year ended December 31, 2024. The decrease of $3.2 million of research and development expenses was primarily a result of the clinical hold imposed on LTI-03. During the year ended December 31, 2025, we spent $5.5 million on clinical trials, $2.4 million on manufacturing, $2.1 million on employee and related expenses, $0.1 million on professional fees and facilities and other expenses, and $0.9 million on regulatory and development consulting. During the year ended December 31, 2024, we incurred expenses of $5.9 million on clinical trials and preclinical studies, $5.5 million on manufacturing including $3.2 million write-offs due to the expiration of clinical materials and the temporary delay of clinical development of LTI-01, and $0.6 million on regulatory and development consulting as well as $2.2 million on employee and related expenses associated with clinical programs acquired in the Lung Acquisition. These programs and related activities were not included in our financial results for periods prior to the Lung Acquisition.

General and Administrative Expenses

	Year Ended December 31,		Increase
	2025	2024	(Decrease)
Employee related expenses	$ 3,748	$ 5,465	$ (1,717)
Professional fees for services	5,191	6,257	(1,066)
Facilities and other expenses	1,963	2,142	(179)
Total general and administrative expenses	$ 10,902	$ 13,864	$ (2,962)

General and administrative expenses were $10.9 million for the year ended December 31, 2025, compared to $13.9 million for the year ended December 31, 2024. The decrease of $3.0 million in general and administrative expenses was primarily due to decreased professional fees of $1.1 million as a result of decrease of $0.8 million in legal expense, and decrease of $1.0 million in other professional fees including accounting fee and audit and tax fees, offset by increased stock compensation expense of $0.7 million due to vesting of restricted stock units granted in exchange for consulting services and the commitment fee related to the Yorkville Transactions recognized during the year ended December 31, 2025, and decreased employee and related expenses of $1.7 million as a result of employee turnover in 2024 as well as decreased facilities and other expenses of $0.2 million.

Impairment Loss on Intangible Assets

We incurred impairment loss on intangible assets of $28.7 million and $37.0 million for the years ended December 31, 2025 and 2024, respectively, in connection with the delay of further clinical development of LTI-01 and other intangible assets which are early-stage programs until additional funds are raised and after LTI-03 is completed. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 for an indefinite period. The timing and likelihood of resuming development are uncertain and contingent on our ability to obtain additional financing and the future success of LTI-03. Therefore, the carrying value of the LTI-01 asset and other preclinical programs was fully written off as of December 31, 2025, which resulted in an impairment loss of $28.7 million for the year ended December 31, 2025. We incurred impairment loss on intangible assets of $37.0 million for the year ended December 31, 2024 in connection with the temporary delay of further clinical development of LTI-01 until additional funds are raised. There were no impairment losses recognized for the LTI-03 asset or goodwill during the years ended December 31, 2025 and 2024.

Other Income, net

Other income, net of less than $0.1 million for the year ended December 31, 2025 primarily consisted of interest income and accretion in our then-current cash and cash equivalents, offset by OID related to the PPA. Other income, net of $0.7 million for the year ended December 31, 2024 consisted of interest income of $0.4 million, investment accretion of $0.3 million, and other income of $0.1 million recognized from the Option Agreement with Advancium. We anticipate that our interest income and investment accretion will fluctuate in the future in response to our then-current cash and cash equivalents, and then-current interest rates.

Income Taxes

As of December 31, 2025, we had federal and state net operating loss carryforwards of $122.7 million and $46.1 million, respectively, which begin to expire in 2036 and 2043, respectively. As of December 31, 2025, we also had federal research and development tax credit carryforwards of $2.5 million, which begin to expire in 2035. We also have federal orphan drug tax credit carryforwards of $5.8 million which begin to expire in 2039.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. As a result of the Lung Acquisition, the tax attributes have been limited under Section 382. We have reflected the reduction of these tax attributes within the income tax footnote at December 31, 2025 and 2024, respectively.

On October 31, 2023, we acquired, in accordance with the terms of the Lung Acquisition Agreement, the stock of Lung. In accordance with Accounting Standards Codification, or ASC, 805, *Business Combinations*, recognition of deferred tax assets and liabilities is required for substantially all temporary differences and acquired tax carryforwards and credits. We have computed estimated temporary differences and acquired tax carryforwards and credits as of the transaction date. We will not have tax basis in intangible assets recorded as part of the purchase. For accounting purposes, the intangible assets will not be amortized and subject to impairment review and testing. Though the tax effects may be delayed indefinitely, ASC 740, *Accounting for Income Taxes,* states that "deferred tax liabilities may not be eliminated or reduced because a reporting entity may be able to delay the settlement of those liabilities by

delaying the events that would cause taxable temporary differences to reverse." As such, we have recorded a deferred tax liability for the portion of the liability that cannot be offset with indefinite lived deferred tax assets.

Liquidity and Capital Resources

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. If we obtain funding for our continued operations, we expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our lead product candidate, LTI-03, or any future product candidates. We expect that our research and development and general and administrative costs would continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our lead product candidates or any future product candidates to support potential future commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company.

As of December 31, 2025, we had cash and cash equivalents of $3.2 million. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2025, together with the $4.3 million of proceeds received by us pursuant to the securities purchase agreements we entered into in January 2026 and February 2026, will be sufficient to enable us to fund our planned operating expense and capital expenditure requirements into the second quarter of 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, strategic collaborations, licensing arrangements or other sources. See the section titled "Risk Factors" found elsewhere in this Annual Report on Form 10-K for risks associated with our substantial capital requirements.

The report of our independent registered accounting firm states that our significant losses, expectation to continue to incur operating losses and need to raise additional funds to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cash used in operating activities	$ (19,361)	$ (22,291)
Cash provided by investing activities	—	—
Cash provided by financing activities	9,755	17,818
Effect of exchange rate changes on cash and cash equivalents	(44)	—
Net decrease in cash and cash equivalents	$ (9,650)	$ (4,473)

Operating Activities

During the year ended December 31, 2025, operating activities used $19.4 million of cash, primarily resulting from our net loss of $49.9 million and a change in operating assets and liabilities of $0.9 million, partially offset by non-cash charges of $31.4 million. Non-cash charges resulted primarily from impairment loss on intangible assets of $28.7 million and stock-based compensation expense of $2.2 million, commitment fee related to the PPA of $0.3 million and OID related to the PPA of $0.2 million. Changes in our operating assets and liabilities during the year ended December 31, 2025 consisted primarily of an increase of $0.3 million in prepaid expenses and other current assets, a decrease of $2.6 million in accrued expenses and other current liabilities, a decrease of $0.3 million in other long-term liabilities, and a decrease of $0.7 million in deferred tax liabilities, offset by an increase of $3.0 million in accounts payable.

During the year ended December 31, 2024, operating activities used $22.3 million of cash, primarily resulting from our net loss of $62.9 million partially offset by a change in operating assets and liabilities of $2.4 million and non-cash charges of $38.2 million. Non-cash charges resulted primarily from impairment loss on intangible assets of $37.0 million and stock-based compensation expense of $1.1 million. Changes in our operating assets and liabilities during the year ended December 31, 2024 consisted primarily of a decrease of $2.2 million in other assets, and an increase of $1.7 million in accrued expenses and other current liabilities, offset by a decrease of $1.6 million in deferred tax liabilities due to the reduction in the carrying value of our intangible assets.

Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $9.8 million primarily due to the April 2025 Transactions, Yorkville Transactions and "at the market" offering programs described above.

During the year ended December 31, 2024, net cash provided by financing activities was $17.8 million primarily due to the Offering in May 2024.

Contractual and other obligations

We enter into contracts in the normal course of business with CROs for clinical and preclinical research studies, external manufacturers for product for use in our clinical trials, and other research supplies and other services as part of our operations. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

In April 2025, we entered into a master services agreement with a third party CRO, under which the CRO has agreed to perform certain services in accordance with written work orders. The work orders set forth the obligations of the parties with regard to conducting the clinical research study entitled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2, Safety, Tolerability and Efficacy Study of Caveolin1-Scaffolding-Protein-Derived Peptide (LTI-03) in Patients with IPF", under our Protocol LTI-03-2001. Pursuant to the agreement, we had contracted for up to $17.0 million of master services. This master services agreement was terminated in August 2025 with no future commitment for the Company.

In December 2025, we entered into a project addendum with a third party CRO for the purposes of setting forth the responsibilities and obligations of the parties in regards to conducting a certain clinical research program entitled "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability and Efficacy of Caveolin-1-Scaffolding-Protein-Derived Peptide in Patients with IPF" under our Protocol LTI-03-2001. Pursuant to the project addendum, we had contracted for up to $19.8 million of master services.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contract and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. Some of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued

expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical and clinical development activities;
- contract research organizations, or CROs, in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials; and
- contract manufacturing organization, or CMOs, or other vendors in connection with the production of preclinical and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage clinical trials and preclinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In recording accrued or prepaid service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the statements of operations and comprehensive loss based on their fair values. We measure stock-based awards based on their fair value on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions and apply the graded-vesting method to all awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

We estimate the fair value of each stock option grant at the date of grant using the Black-Scholes option pricing model and the fair value of each restricted common stock award is estimated on the date of grant based on the fair value of our common stock on that same date. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions including the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Changes to these assumptions can materially affect the fair value of stock options and ultimately the amount of stock-based compensation expense recognized in our consolidated financial statements.

We account for stock option forfeitures during the period in which they occur.

Impairment on Indefinite-lived Intangible Assets

We review our intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Indefinite-lived intangible assets, including goodwill, are tested for impairment at least annually. The fair value of reporting unit was determined using the income approach with a reconciliation to market capitalization. The fair value of intangible assets was determined using multi-period excess earning method and using Level 3 inputs, which included estimates of forecasted cash flows for each candidate.

Impairment is assessed by comparing the carrying value of the asset to its recoverable amount, which is determined as the higher of its fair value less costs to sell and its value in use. The value in use is estimated based on discounted future cash flows derived from assumptions regarding revenue growth, operating margins, discount rates, and market conditions. These estimates require significant management judgment and are subject to inherent uncertainties.

Key assumptions used in impairment testing include:

- Projected cash flows: Based on market analysis and business forecasts.
- Discount rate: Reflecting the risk-adjusted cost of capital applicable to the asset or cash-generating unit.
- Growth rate: Used for terminal value calculations, based on long-term industry outlook and economic conditions.
- Market conditions: Including competitive landscape, industry trends, and macroeconomic factors.

Changes in these assumptions, particularly in discount rates or expected future cash flows, could result in significant adjustments to the impairment calculation and may lead to impairment losses recognized in the financial statements.

During the years ended December 31, 2025 and 2024, we conducted an impairment assessment and determined that an impairment loss of $28.7 million and $37.0 million, respectively, was recognized for our LTI-01 intangible asset and other preclinical programs. In the fourth quarter of 2024, we determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, we decided to pause development activities related to LTI-01 and other preclinical programs for an indefinite period. The timing and likelihood of resuming development are uncertain and contingent on our ability to obtain additional financing and the future success of LTI-03. Therefore, the carrying value of the LTI-01 asset and other preclinical programs was fully written off as of December 31, 2025. There were no impairment losses recognized for our LTI-03 asset or goodwill during the years ended December 31, 2025 and 2024.

Management continues to monitor these estimates and will adjust them as necessary to reflect changing economic conditions and business performance.

Income Taxes

We account for income taxes using 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 recognized in the financial statements or in our tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Changes in valuation allowances from period to period are included in our tax provision in the period of change. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

The recognition and measurement of tax benefits requires significant judgment, especially in assessing uncertain tax positions. Judgments concerning the recognition and measurement of our tax benefits, as well as limitations surrounding their realizability, might change as new information becomes available.

Global and Macroeconomic Developments

We are subject to continuing risks and uncertainties in connection with legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, instability in financial institutions, the ongoing conflicts in Ukraine and in the Middle East. Most of these developments and factors are outside of our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources. For additional information, see the section titled "Risk Factors" found elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2025.

Smaller Reporting Company Status

We are a "smaller reporting company" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700.0 million. For so long as we continue to be a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, such standards will not have a material impact on our consolidated financial statements or do not otherwise apply to our operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act for this reporting period and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those consolidated financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Inapplicable.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a

company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our interim Chief Financial Officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and our interim Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2025, because of the identified material weaknesses in our internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was not effective as of December 31, 2025 as a result of the material weaknesses discussed below.

Material Weaknesses

We identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. We identified the following material weaknesses in internal control over financial reporting: (i) lack of sufficient

accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and (ii) lack of adequate procedures and controls to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual reporting purposes.

Management's Plan to Remediate the Material Weaknesses

The below are actions that we have taken to date to remediate the above-mentioned material weaknesses:

- Enhanced the execution of our risk assessment activities by evaluating whether the design of our internal controls appropriately addresses changes in the business (including changes to people, processes and systems) that could impact our system of internal controls.
- Completed the integration of the acquired systems from the Lung Acquisition into our financial and accounting systems to allow for systematic segregation of duties, and to enhance the accurate and timely preparation and review of financial statements and supporting schedules.
- Engaged a third-party to assist in assessing the design and implementation of controls and develop remediation plans for identified control gaps related to our timely preparation and review of account reconciliations, financial statements and supporting schedules.
- Reported regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.
- Continued to reassess staffing and add additional resources, as required, with the requisite technical accounting experience and training, to further allow for segregation of duties and to support our system of internal control.

In addition to implementing and executing the aforementioned activities, the following activities are expected to be completed in fiscal year 2026:

- Implement remediation plans for identified control design and implementation gaps.
- Continue to act upon the enhancements to our internal controls that we implemented in 2025.
- Perform testing of operating effectiveness of identified controls over financial reporting including IT General Controls.
- As needed, we will also supplement our internal resources with additional third-party resources to enhance our corporate oversight and monitoring over process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability.

The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Management believes that the remediation measures described above will be implemented in a manner such that the controls can be tested, and the identified material weaknesses can be determined to be remediated, however, no assurance can be made that such remediation will occur or that additional material weaknesses will not be identified.

Changes in Internal Control Over Financial Reporting

In connection with our December 31, 2024 10-K, a material weakness in our internal control over financial reporting was identified relating to segregation of duties within our financial accounting system and lack of reviews of account reconciliation and supporting schedules. Management implemented measures designed to ensure that the control deficiencies related to the material weaknesses were remediated, such that the controls are designed, implemented and operating effectively. The remediation actions included hiring of additional accounting personnel which allowed for proper segregation of duties within the financial accounting system and the implementation of internal controls related to the account reconciliation process. Other than the changes to remediate the material weaknesses and the related ongoing remediation activities described above, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the year

ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

During the fourth quarter of 2025, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission, or the SEC, with respect to our 2026 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the end of our last fiscal year ended December 31, 2025 and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the text of our Code of Business Conduct and Ethics under the "Investors & Media — Governance" section of our website, www.reintx.com. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the end of our last fiscal year ended December 31, 2025 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the end of our last fiscal year ended December 31, 2025 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the end of our last fiscal year ended December 31, 2025 and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the end of our last fiscal year ended December 31, 2025 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this Report:

(a) *Financial Statements*. The following documents are included on pages F6-F38 attached hereto and are filed as part of this Annual Report on Form 10-K:

(b) *Financial Statement Schedules*. Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(c) *Exhibits*. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index below. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description	Incorporation by Reference			Filed Herewith
		Form	Date of Filing	Exhibit Number	
2.1#	Agreement and Plan of Merger, dated October 31, 2023, by and among Aileron Therapeutics, Inc., AT Merger Sub I, Inc., AT Merger Sub II, LLC and Lung Therapeutics, Inc.	8-K	10/31/2023	2.1	
3.1	Restated Certificate of Incorporation of the Registrant, as amended	10-Q	8/11/2021	3.1	
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, dated as of November 10, 2022	8-K	11/10/2022	3.1	
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, dated as of February, 29, 2024	10-K	4/15/2024	3.3	
3.4	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, dated as of January 10, 2025	8-K	1/10/2025	3.1	
3.5	Amended and Restated By-laws of the Registrant	8-K	1/10/2025	3.2	
4.1	Specimen stock certificate evidencing shares of common stock	S-1^	6/19/2017	4.1	
4.2	Description of Securities of the Registrant	10-K	4/15/2024	4.2	
4.3	Certificate of Designation of Series X Non-Voting Convertible Preferred Stock	8-K	10/31/2023	3.1	
4.4	Form of Warrant to Purchase Common Stock issued pursuant to the Stock and Warrant Purchase Agreement	8-K	10/31/2023	4.1	
10.1*	2016 Stock Incentive Plan	S-1^	6/2/2017	10.4	

10.2*	Form of Incentive Stock Option Agreement under 2016 Stock Incentive Plan	S-1^	6/2/2017	10.5
10.3*	Form of Nonstatutory Stock Option Agreement under 2016 Stock Incentive Plan	S-1^	6/2/2017	10.6
10.4*	2017 Stock Incentive Plan	S-1^	6/19/2017	10.8
10.5*	Form of Incentive Stock Option Agreement under 2017 Stock Incentive Plan	S-1^	6/19/2017	10.9
10.6*	Form of Nonstatutory Stock Option Agreement under 2017 Stock Incentive Plan	S-1^	6/19/2017	10.10
10.7*	2017 Employee Stock Purchase Plan	S-1^	6/19/2017	10.11
10.8*	Aileron Therapeutics, Inc. 2021 Stock Incentive Plan, as amended	10-K	4/15/2024	10.11
10.9*	Form of Stock Option Agreement under 2021 Stock Incentive Plan	10-K	3/20/2023	10.12
10.10*	Form of Restricted Stock Unit Agreement under 2021 Stock Incentive Plan	10-K	3/20/2023	10.13
10.11	Form of Director and Officer Indemnification Agreement	S-1^	6/19/2017	10.12
10.13*	Consulting Agreement, dated as of April 15, 2023, between the Registrant and D. Allen Annis, Ph.D.	10-Q	5/8/2023	10.2
10.14	Waiver Under Amended and Restated License Agreement, dated as of February 19, 2010, by and among the Registrant, President and Fellows of Harvard College and Dana-Farber Cancer Institute, Inc.	10-Q	10/13/2023	10.1
10.15#	Stock and Warrant Purchase Agreement, dated as of October 31, 2023, by and among Aileron Therapeutics, Inc. and each purchaser identified on Annex A thereto	8-K	10/31/2023	10.1
10.16	Form of Registration Rights Agreement, by and among Aileron Therapeutics, Inc. and certain purchasers named therein	8-K	10/31/2023	10.2
10.17*	Executive Employment Agreement, dated as of February 1, 2014, by and between Lung Therapeutics, Inc. and Brian Windsor, Ph.D., as amended	8-K	10/31/2023	10.3
10.18*	Letter Agreement, dated as of February 11, 2023, by and between Lung Therapeutics, Inc. and Brian Windsor, Ph.D.	8-K	10/31/2023	10.4
10.19*	Letter Agreement, dated as of October 30, 2023, by and between Lung Therapeutics, Inc. and Brian Windsor, Ph.D.	8-K	10/31/2023	10.5
10.20+#	Exclusive License Agreement, dated as of November 12, 2020, by and between Lung Therapeutics, Inc. and Taiho Pharmaceutical Co. Ltd.	8-K	1/25/2024	10.1

10.21+	Amended and Restated Patent and Technology License Agreement, effective as of December 19, 2013, by and between Lung Therapeutics, Inc. and the Board of Regents of The University of Texas System, on behalf of The University of Texas Health Science Center at Tyler, as amended by First Amendment, effective as of May 4, 2017.	8-K	1/25/2024	10.2	
10.22+	Patent License Agreement, effective as of May 21, 2015, by and between Lung Therapeutics, Inc. and the University of Texas at Austin, on behalf of The University of Texas System, as amended by Amendment #1, dated as of January 26, 2017, Amendment #2, dated as of November 19, 2018, Amendment #3, effective as of June 20, 2019, and Amendment #4, dated as of April 28, 2023.	8-K	1/25/2024	10.3	
10.23+	Amended and Restated License Agreement, effective as of September 1, 2018, by and between Lung Therapeutics, Inc. and Medical University of South Carolina Foundation for Research Development.	8-K	1/25/2024	10.4	
10.24+	License Agreement, effective as of March 8, 2018, by and between Lung Therapeutics, Inc. and Vivarta Therapeutics, L.L.C.	8-K	1/25/2024	10.5	
10.25*	Lung Therapeutics, Inc.2013 Long-Term Incentive Plan, as amended	10-K	4/15/2024	10.42	
19.1*	Rein Insider Trading Policy				X
21.1	Subsidiaries of Rein Therapeutics, Inc.	10-K	4/15/2024	21.1	
23.1	Consent of CBIZ CPAs PC, independent registered public accounting firm				X
23.2	Consent of Marcum LLP, independent registered public accounting firm				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1	Rein Therapeutics, Inc. Compensation Recovery Policy	10-K	4/15/2024	97.1	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Indicates management contract or compensatory plan.

+ In accordance with Item 601(b)(10)(iv) of Regulation S-K, certain information (indicated by "[**]") has been excluded from this exhibit because it is both not material and private or confidential. A copy of the omitted portion will be furnished to the SEC upon request.

++ Confidential treatment has been requested and/or granted as to certain portions, which portions have been omitted and filed separately with the SEC.

Certain schedules and similar attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

^ SEC File No. 333-218474

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Rein Therapeutics, Inc.

Date: March 26, 2026

By: /s/ Brian Windsor, Ph.D.
Brian Windsor, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Brian Windsor, Ph.D. **Brian Windsor, Ph.D.**	President, Chief Executive Officer and Director (principal executive officer)	March 26, 2026
/s/ Timothy M. Cunningham **Timothy M. Cunningham**	Interim Chief Financial Officer (principal financial officer and principal accounting officer)	March 26, 2026
/s/ Josef H. Von Rickenbach **Josef H. Von Rickenbach**	Chairman of the Board of Directors	March 26, 2026
/s/ Reinhard J. Ambros, Ph.D. **Reinhard J. Ambros, Ph.D.**	Director	March 26, 2026
/s/ William C. Fairey **William C. Fairey**	Director	March 26, 2026
/s/ Alan Musso **Alan Musso**	Director	March 26, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Rein Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Rein Therapeutics Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Goodwill and Indefinite-Lived Intangible Assets Impairment Assessment

Critical Audit Matter Description

As described in Note 5 to the consolidated financial statements, the Company's consolidated balances of Goodwill and In-process Research and Development ("IPR&D") indefinite-lived intangible assets were $6.3 million and $13.5 million, respectively, as of December 31, 2025. The Company reviews goodwill for impairment at least annually or more frequently if events or circumstances indicate the carrying value at the reporting unit level might exceed its fair value. The IPR&D indefinite-lived intangibles are tested annually for impairment, or more frequently if events or circumstances indicate it is more likely than not the fair value is less than their carrying value. The Company estimated the fair value of its reporting unit using an income approach. The Company estimated the fair value of certain IPR&D assets using a multi period excess earnings model. The Company performed impairment analyses for IPR&D and Goodwill, which resulted in an impairment charge of $28.7 million relating to the IPR&D and no impairment relating to Goodwill.

The principal consideration, for our determination that the evaluation of the fair values of the indefinite-lived intangible assets and the Company's reporting unit, as a critical audit matter is the high degree of subjective auditor judgment associated with evaluating management's determination of the fair values, which is primarily due to the complexity of the valuation models used and the sensitivity of the underlying significant assumptions.

The key assumptions used in the determination of the fair value of the reporting unit include estimates of future cash flows and the discount rate applicable to those future cash flow periods. The key assumptions used in the determination of the fair value of certain IPR&D assets include estimates of future cash flows, the probability of success in various phases of its development programs, the discount rate applicable to those future cash flow periods, the tax rate and the timing of regulatory approval. Changes to these key assumptions could have a significant impact on the measurement of the fair value of the reporting unit and certain IPR&D. Auditing management's valuation methods and these assumptions involve especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address these matters, including the specialized knowledge and skill needed.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to the valuation of the fair values of goodwill and indefinite-lived intangible assets included the following, among others:

- We evaluated the reasonableness of the valuation analysis from management and the third-party specialist engaged by management.
- We assessed the qualifications and competence of management and the third-party specialist.

- We evaluated the methodologies used to determine the fair values of the indefinite-lived intangible assets and goodwill.
- We tested the assumptions used to estimate the fair values, which included key assumptions such as the estimates of future cash flows, the probability of success in various phases of its development programs, the discount rate applicable to those future cash flow periods, the tax rate, and the timing of regulatory approval.
- We assessed the reasonableness of management's forecast of estimated future cash flows by inquiring with management to understand how the forecast was developed and comparing the projections to external sources including industry trends and data and peer companies' historical data.
- We involved our internal valuation specialist who assisted in (i) evaluating the reasonableness of valuation methods, (ii) testing the mathematical accuracy of the Company's calculations, (iii) evaluating the reasonableness of the implied control premium; and (iv) evaluating the reasonableness of the significant assumptions to the models, including the discount rate applied to future cash flows.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2024 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

New York, NY
March 26, 2026

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Rein Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Rein Therapeutics Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and expects to continue to incur operating losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor from 2024 to 2025.

New York, NY
April 7, 2025

REIN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 3,215	$ 12,865
Prepaid expenses and other current assets	1,111	792
Total current assets	4,326	13,657
Property and equipment, net	—	1
Goodwill	6,330	6,330
Intangible assets	13,500	42,200
Other non-current assets	2	2
Total assets	$ 24,158	$ 62,190
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,976	$ 911
Accrued expenses and other current liabilities	2,204	4,838
Total current liabilities	6,180	5,749
Deferred tax liability	1,060	1,772
Other long-term liability	—	277
Total liabilities	7,240	7,798
Commitments and contingencies (Note 12)		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2025 and at December 31, 2024; 24,610 shares issued and 12,232 shares outstanding at December 31, 2025 and at December 31, 2024	45,005	45,005
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2025 and at December 31, 2024; 27,550,222 shares and 21,666,012 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	113	108
Additional paid-in capital	373,133	360,697
Accumulated other comprehensive loss	(62)	(18)
Accumulated deficit	(401,271)	(351,400)
Total liabilities, convertible preferred stock and stockholders' equity	$ 24,158	$ 62,190

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

REIN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Revenue	$ —	$ —
Operating expenses:		
Research and development	11,029	14,248
General and administrative	10,902	13,864
Impairment loss on intangible assets	28,700	37,000
Total operating expenses	50,631	65,112
Loss from operations	(50,631)	(65,112)
Other income, net	48	685
Income tax benefit	712	1,544
Net loss	$ (49,871)	$ (62,883)
Net loss per share—basic and diluted	$ (1.96)	$ (3.51)
Weighted average common shares outstanding—basic and diluted	25,444,795	17,938,899
Comprehensive loss:		
Net loss	$ (49,871)	$ (62,883)
Other comprehensive gain (loss):		
Unrealized (loss) gain on investments, net of tax of $0	(15)	45
Foreign currency translation adjustments	(29)	—
Total other comprehensive (loss) gain	(44)	45
Total comprehensive loss	$ (49,915)	$ (62,838)

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

REIN THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(In thousands, except share data)

	Series X Non-Voting Convertible Preferred Stock		Common Stock					Total Convertible
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Preferred Stock and Stockholders' Equity
Balances at December 31, 2023	24,610	$91,410	4,885,512	$91	$295,376	$(63)	$(288,517)	$98,297
Issuance of common stock in connection with conversion of Series X non-voting convertible preferred stock	(12,378)	(46,405)	12,378,000	12	46,392	—	—	(1)
Issuance of common stock	—	—	4,273,505	4	10,933	—	—	10,937
Issuance of warrants	—	—	—	—	7,225	—	—	7,225
Issuance cost in connection with the Offering	—	—	—	—	(488)	—	—	(488)
Stock-based compensation expense	—	—	—	—	1,117	—	—	1,117
Exercises of stock options	—	—	128,995	1	142	—	—	143
Unrealized gain on investments	—	—	—	—	—	45	—	45
Net loss	—	—	—	—	—	—	(62,883)	(62,883)
Balances at December 31, 2024	12,232	$45,005	21,666,012	$108	$360,697	$(18)	$(351,400)	$54,392
Issuance of common stock for Pre-Paid Advances	—	—	2,727,162	2	3,009	—	—	3,011
Issuance of common stock for commitment fee	—	—	213,099	—	300	—	—	300
Issuance of common stock in connection with "at the market" offerings	—	—	1,317,739	1	1,818	—	—	1,819
Issuance of warrants	—	—	—	—	481	—	—	481
Issuance of common stock in connection with Warrant Exercises	—	—	1,035,758	1	1,594	—	—	1,595
Warrant Exchanges	—	—	—	—	2,984	—	—	2,984
Stock-based compensation expense	—	—	—	—	2,224	—	—	2,224
Exercises of stock options	—	—	10,452	—	4	—	—	4
Vesting of restricted stock units	—	—	580,000	1	—	—	—	1
Common Stock to be issued upon Warrant Exercises	—	—	—	—	22	—	—	22
Unrealized gain on investments	—	—	—	—	—	(15)	—	(15)
Foreign currency translation adjustments	—	—	—	—	—	(29)	—	(29)
Net loss	—	—	—	—	—	—	(49,871)	(49,871)
Balance at December 31, 2025	12,232	$45,005	27,550,222	$113	$373,133	$(62)	$(401,271)	$16,918

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

REIN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (49,871)	$ (62,883)
Adjustments to reconcile net loss to net cash used in operating activities:		
Commitment fee related to Pre-Paid Advance agreement	300	—
Original issue discount related to Pre-Paid Advance agreement	150	—
Depreciation and amortization expense	1	63
Stock-based compensation expense	2,224	1,117
Impairment loss on intangible assets	28,700	37,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(319)	134
Other assets	—	2,191
Accounts payable	3,065	(279)
Operating lease liabilities	—	(48)
Accrued expenses and other current liabilities	(2,622)	1,691
Other long-term liabilities	(277)	277
Deferred tax liabilities	(712)	(1,554)
Net cash used in operating activities	(19,361)	(22,291)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of offering costs	1,819	10,645
Proceeds from Pre-Paid Advances, net of discounts	2,850	—
Proceeds from issuance of common stock in connection with stock option exercises	4	143
Proceeds from issuance of common stock in connection with Warrant Exercises, net of costs	1,595	—
Proceeds from issuance of warrants, net of offering costs	481	7,030
Proceeds from Warrant Exchanges, net of offering costs	2,984	—
Proceeds from warrant exercises with common stock subscribed	22	—
Net cash provided by financing activities	9,755	17,818
Effect of exchange rate changes on cash and cash equivalents	(44)	—
Net decrease in cash and cash equivalents	(9,650)	(4,473)
Cash and cash equivalents at beginning of year	12,865	17,338
Cash and cash equivalents at end of year	$ 3,215	$ 12,865
Cash and cash equivalents at end of year	$ 3,215	$ 12,865
Cash and cash equivalents at end of year	$ 3,215	$ 12,865
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized (loss) gain on short-term investments	$ (15)	$ 37
Foreign currency translation adjustments	$ (29)	$ —
Issuance of common stock for Pre-Paid Advances and interest accrual	$ 3,011	$ —
Conversion of Series X non-voting convertible preferred stock into common stock shares	$ —	$ 46,405

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

REIN THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share data)

1. Nature of the Business

On January 10, 2025, Aileron Therapeutics, Inc., or Aileron, amended its Restated Certificate of Incorporation, as amended, to effect a change of the Company's name from "Aileron Therapeutics, Inc." to "Rein Therapeutics, Inc.", or Rein, or the Company.

Prior to the Lung Acquisition (as defined below), the Company was a clinical stage chemoprotection oncology company. The Company's product candidate, ALRN-6924, was a MDM2/MDMX dual inhibitor that leverages its proprietary peptide drug technology. In February 2023, the Company decided to terminate further development of ALRN-6924. On October 31, 2024, the Company entered into an exclusive option agreement with Advancium Health Network, or Advancium, for the sale of ALRN-6924. In July 2025, the option agreement was terminated. In August 2025, the Company entered into a letter agreement with Rients LLC, or Rients, for Rients to evaluate the legacy ALRN-6924 compound, or the Compound Asset. During the term of the letter agreement, Rients shall pay the Company for all fees and expenses incurred by the Company to maintain the Compound Asset.

The Company is a clinical stage biopharmaceutical company focused on developing novel therapies for the treatment of fibrosis indications with no approved or limited effective treatments. The Company currently has one product candidate in clinical development, LTI-03. Development of another product candidate, LTI-01, as well as multiple candidates in preclinical development focused on fibrosis indications were postponed for an indefinite period due to insufficient financing as disclosed below.

On October 31, 2023, the Company acquired Lung Therapeutics, Inc., or Lung Therapeutics or Lung, pursuant to an Agreement and Plan of Merger, dated October 31, 2023, or the Lung Acquisition Agreement, by and among the Company, AT Merger Sub I, Inc., a Delaware corporation and its wholly owned subsidiary, or the First Merger Sub, AT Merger Sub II, LLC, a Delaware limited liability company and its wholly owned subsidiary, or the Second Merger Sub, and Lung. Its principal offices are in Austin, Texas. Following the Lung Acquisition, the Company shifted its operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications with the potential to greatly improve patient outcomes over currently available treatments. Following expiration of the lease on March 31, 2024, Rein currently operates and expects to operate virtually for the foreseeable future.

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to the risk that the Company never achieves profitability, the need for substantial additional financing, the risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology, and compliance with government regulations. The Company's lead product candidate, LTI-03, is being developed for the treatment of Idiopathic Pulmonary Fibrosis, or IPF, and has been evaluated in a healthy volunteer Phase 1a clinical trial and in a Phase 1b clinical trial in IPF patients. A Phase 2 multi-center, randomized, double-blind, and placebo-controlled study evaluating the safety, tolerability, and efficacy of LTI-03 in patients with IPF will enroll up to 120 IPF patients with interim topline data expected in the second half of 2026. The Company's second product candidate, LTI-01, was in development for loculated pleural effusion, or LPE. The Company has completed Phase 1b and Phase 2a clinical trials in LPE patients. In June 2024, the Company decided to temporarily delay clinical development of LTI-01 in an effort to focus its resources on clinical development of LTI-03 and until additional funds are raised. In the fourth quarter of 2024, the Company determined that the temporary delay of further clinical development of LTI-01 may not be a short-term measure. In the fourth quarter of 2025, the Company decided to pause development activities related to LTI-01 for an indefinite period. The timing and likelihood of resuming development are uncertain and contingent on the Compamy's ability to obtain additional financing and the future success of LTI-03.

In May 2025, the Company initiated screening and recruitment of patients in the RENEW Phase 2 clinical trial of LTI-03. The RENEW trial is a Phase 2 multi-center, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, and efficacy of LTI-03 patients with IPF. In addition, the trial is designed to assess the activity of inhaled dry powder LTI-03 across multiple biomarkers and to measure lung function, lung imaging markers of fibrosis, and the potential for healthy tissue regeneration. The trial is designed to enroll approximately 120 patients diagnosed with IPF within 5 years of screening, who may be receiving standard of care antifibrotic therapy, across up to 50 sites globally, including sites in the U.S., UK, Germany, Australia and Poland. Patients will be randomized into two blinded placebo-controlled cohorts that will run concurrently. Patients in the low dose cohort will receive 2.5 mg

of either LTI-03 or placebo administered twice daily, or BID, for a total dose of 5 mg/day, while participants in the high dose cohort will receive 5 mg BID for a total dose of 10 mg/day. The primary endpoint is the incidence of treatment-emergent adverse events from Day 1 through Week 24. The key secondary endpoint is the efficacy of LTI-03 measured through forced vital capacity, percent predicted FVC and high-resolution computer tomography, in collaboration with Qureight Ltd. Patients will undergo a 28-day screening period prior to being randomized and entering the 24-week treatment period, with a four-week follow-up.

In October 2025, the Company received authorization from the European Medicines Agency, or the EMA, to initiate its Phase 2 RENEW trial of its lead candidate, LTI-03, for the treatment of IPF at sites in Germany and Poland. The Company had previously received regulatory clearance from the UK's Medicines and Healthcare products Regulatory Agency, or the MHRA. In January 2026, the Company received orphan drug designation from the EMA for LTI-03.

As of the date of this Annual Report, the Company activated sites and is enrolling patients in the U.S. and is seeking to activate additional sites, enroll patients and initiate the RENEW trial throughout the U.S., UK, Europe and other jurisdictions. In March 2026, the Company dosed its first patient in the RENEW Phase 2 clinical trial of LTI-03. The Company expects to report initial interim topline data on some proportion of patients in the fourth quarter of 2026.

Liquidity and Going Concern

In accordance with Accounting Standards Update, or ASU, No. 2014-15, *Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the consolidated financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the consolidated financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the consolidated financial statements are issued.

The Company's consolidated financial statements have been prepared assuming that the Company will continue to operate as a going concern, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through December 31, 2025, the Company has financed its operations primarily through $145,467 in net proceeds from sales of common stock and warrants, $2,201 in net proceeds from sales of common stock under its "at the market" offering programs, $131,211 from sales of preferred stock prior to its initial public offering, or IPO, $34,910 from a collaboration agreement in 2010, $17,536 in net proceeds in connection with a private placement following the Lung Acquisition in 2023, $17,675 in net proceeds in connection with an underwritten offering of the Company's common stock and accompanying warrants to purchase common stock in May 2024, $5,082 in net proceeds from the April 2025 Transactions (as defined below) and $2,850 in net proceeds from the Yorkville Transactions described below. As of December 31, 2025, the Company had $3,215 in cash and cash equivalents.

In May 2024, the Company completed an underwritten follow-on public offering, or the Offering, pursuant to which the Company issued and sold 4,273,505 shares of the Company's common stock, par value $0.001 per share, or the Offering Shares, and accompanying warrants, or the Offering Warrants, to purchase 4,273,505 shares of common stock, or the Offering Warrant Shares. All of the Offering Shares and Offering Warrants were sold by the Company. Each Offering Share was offered and sold together with an accompanying Offering Warrant at a combined public offering price of $4.68, and the underwriter purchased each Offering Share with an accompanying Offering Warrant from the Company, after the underwriting discount, at a combined price of $4.35. Net proceeds from the Offering were $17,675, after deducting underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the Offering Warrants. The Offering Warrants to purchase 890,138 shares of common stock were exercised in April 2025 as part of April 2025 Transactions (as defined below). As of December 31, 2025, Offering Warrants to purchase 3,388,707 shares of common stock remained outstanding.

In April 2025, the Company entered into privately negotiated letter agreements with certain holders of the PIPE Warrants, as described in Note 3, and certain holders of the Offering Warrants, who agreed to exercise for cash the PIPE Warrants and the Offering Warrants, or the Warrant Exercises as further discussed in Note 8. The total gross proceeds for the Warrant Exercises were $1,679. Also in April 2025, the Company entered into privately negotiated letter agreements with additional holders of the PIPE Warrants who, in exchange for pre-funded warrants, or the Exchange Pre-Funded Warrants, surrendered PIPE Warrants to the Company for cancellation and made an aggregate cash payment into which the Exchange Pre-Funded Warrants are exercisable, or the Warrant Exchanges as further discussed in Note 8. The total gross proceeds for the Warrant Exchanges were $3,101. In addition, an entity affiliated with Bios Partners, or the Bios Purchaser, purchased additional pre-funded warrants in a private placement, or the Placement Pre-Funded Warrants, pursuant to a subscription agreement underlying the Placement Pre-Funded Warrants, or the Private Placement. Total gross proceeds for the Private Placement were $500. The Warrant Exercises, Warrant Exchanges and Private Placement are collectively referred to as the April 2025 Transactions.

On May 15, 2025, the Company entered into an "at the market offering" agreement, or the Wainwright Sales Agreement, with H.C. Wainwright & Co., LLC, or H.C. Wainwright, as agent and/or principal, pursuant to which the Company could offer and sell shares of its common stock having an aggregate offering price of up to $13,702 from time to time through or to H.C. Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of December 31, 2025, the Company had issued and sold 999,967 shares of common stock pursuant to the Wainwright Sales Agreement for total net proceeds of $1,489, after deducting transaction fees of $52 paid by the Company. In July 2025, in connection with the Yorkville Transactions, the Company reduced the aggregate offering price of the shares of common stock that could be offered and sold under the Wainwright Sales Agreement to $8,067.

Prior to entering into the Wainwright Sales Agreement, in May 2025, the Company terminated the equity distribution agreement, dated July 26, 2024, or the Equity Distribution Agreement, with Citizens JMP Securities, LLC, or Citizens JMP, as agent and/or principal, under which the Company could offer and sell up to $50,000 of shares of its common stock from time to time through or to Citizens JMP by any method that was deemed an "at the market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. In January 2025, the Company issued and sold 317,772 shares of common stock pursuant to the Equity Distribution Agreement for total net proceeds of $712, after deducting transaction fees of $22 paid by the Company. The Company did not issue or sell any other shares of common stock pursuant to the Equity Distribution Agreement during the year ended December 31, 2025. The Company did not sell any shares of common stock pursuant to the Equity Distribution Agreement during the year ended December 31, 2024.

In July 2025, the Company entered into a Pre-Paid Advance Agreement, or the PPA, and a Standby Equity Purchase Agreement, or the SEPA, with YA II PN, Ltd., a Cayman Islands exempt limited partnership, or Yorkville. The PPA and the SEPA are collectively referred to as the Yorkville Transactions. In accordance with the terms of the PPA, the Company may request pre-paid advances of up to $6,000 from Yorkville (each, a "Pre-Paid Advance") over a 12-month period, subject to certain limitations and conditions set forth in the PPA. Each Pre-Paid Advance will be purchased by Yorkville at 95% of the face amount of the Pre-Paid Advance. At any time there is an outstanding balance under any Pre-Paid Advances, Yorkville may provide written notice requiring the Company to issue and sell shares of its common stock to Yorkville, which shall be offset against and reduce the amounts outstanding under the Pre-Paid Advances. An initial Pre-Paid Advance of $1,000 was purchased on July 29, 2025 by Yorkville, or the First Advance, for net proceeds of $950. On September 8, 2025, Yorkville purchased a second Pre-Paid Advance, or the Second Advance, of $1,000, for which the Company received net proceeds of $950. On October 23, 2025, Yorkville purchased a third Pre-Paid Advance, or the Third Advance, of $1,000, for which the Company received net proceeds of $950. As of December 31, 2025, Yorkville has converted the entire initial Pre-Paid Advance, in the aggregate amount of $1,007 of principal and accrued interest, into 953,765 shares of the Company's common stock, at a weighted average price per share of approximately $1.056, converted the Second Advance, in the aggregate amount of $1,004 of principal and accrued interest, into 927,107 shares of the Company's common stock, at a weighted average price per share of approximately $1.082, and converted the Third Advance, in the aggregate amount of $1,001 of principal and accrued interest, into 846,290 shares of the Company's common stock, at a weighted average price per share of approximately $1.183. Separately, under the SEPA, the Company may sell up to $15,000 of its common stock to Yorkville over a 36-month term. The Company has the sole discretion to initiate such sales, subject to volume and pricing limitations. In connection with entry into the SEPA, the Company paid Yorkville a $300 commitment fee through the issuance of 213,099 shares of common stock and paid $25 in structuring and legal fees. As of the date of this report, the Company has not elected to sell any shares of common stock to Yorkville under the SEPA. In December 2025, the Company elected to terminate the PPA and SEPA.

Management believes that, based on the Company's current operating plan, the Company's cash and cash equivalents of $3,215 as of December 31, 2025, together with the proceeds received by the Company pursuant to the securities purchase agreements it entered into in January 2026 and February 2026, will be sufficient to enable the Company to fund its planned operating expense and capital expenditure requirements into the second quarter of 2026. The funds are not sufficient to enable the Company to complete the Phase 2 RENEW clinical trial of LTI-03. The Company's estimate as to how long it expects its existing cash and cash equivalents to be able to continue to fund its operations is based on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects. In addition, the Company's cash and cash equivalents will not be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of these consolidated financial statements, which raises substantial doubt about the Company's ability to continue as a going concern.

Since its inception, the Company has not generated any revenue from product sales and has never generated an operating profit. The Company has incurred significant losses on an aggregate basis. The Company's net losses were $49,871 and $62,883 for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $401,271. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment and general and administrative costs associated with the Company's operations. The Company expects to continue to incur operating losses for the foreseeable future. The Company expects to finance its operations primarily through utilization of its current financial resources and through the sale of additional equity or debt financings, collaborations, licensing arrangements or other sources.

The Company plans to seek to raise additional funds through equity or debt financings, strategic collaborations, licensing arrangements or other sources. However, there is no assurance that such funding will be available to the Company, will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The Company's funding estimates are based on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects. If additional funds are not available, the Company could be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts and its business could be materially harmed. The Company's future viability is dependent on its ability to raise additional capital, enter into a financing, consummate a successful acquisition, merger, business combination, or sale of assets or other transaction. If the Company becomes unable to continue as a going concern, it may have to liquidate its assets and the values it receives for its assets in liquidation or dissolution could be significantly lower than the values reflected in its consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and as amended by ASUs of the Financial Accounting Standards Board, or FASB.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Lung Therapeutics, LLC, Lung Therapeutics Australia Pty Ltd, and Lung Therapeutics Limited. Lung Therapeutics Limited is currently inactive. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses, the prepaid research and development expenses, valuation of intangibles and goodwill, the valuation of warrants, and the value of stock-based

compensation. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Foreign Currency Transactions

The functional currency for the Company's wholly owned foreign subsidiary, Lung Therapeutics Australia Pty Ltd., is the United States dollar. All foreign currency transaction gains and losses are recognized in the consolidated statements of operations and comprehensive loss.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Periodically, the Company maintains balances in operating accounts above federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality. 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.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relied on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could have been adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Cash and Cash Equivalents

The Company maintains cash balances in various accounts, including those insured by the Federal Deposit Insurance Corporation (FDIC). The FDIC provides insurance coverage up to applicable limits for deposits held in participating financial institutions. At various times, the Company has deposits in these financial institutions in excess of the amount insured by the FDIC.

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at the acquisition date to be cash equivalents. The Company's cash equivalents are comprised of funds held in money market accounts and treasury bills account and are measured at fair value on a recurring basis.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. ASC 820, *Fair Value Measurement*, or ASC 820, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable.

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Goodwill and Indefinite-Lived Intangible Assets

Goodwill represents the excess of the purchase price of an acquired business over the amount assigned to the assets acquired and liabilities assumed. The Company's indefinite-lived intangible assets, which consist of in-process research and development, or IPR&D, acquired in the Lung Acquisition were recorded at fair value on their acquisition date. Goodwill and indefinite-lived intangible assets are not amortized but are subject to impairment testing on an annual basis as of December 31 or more frequently if events or circumstances indicate a potential impairment. The Company accounts for goodwill and indefinite-lived intangible assets in accordance with ASC 350, *Intangibles Goodwill and Other*, and ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The Company's goodwill and intangible assets are not deductible for tax purposes.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment, goodwill and intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

In performing the Company's annual goodwill impairment test, the Company is permitted to first assess qualitative factors to determine whether it is more likely than not that the fair value of the Company's reporting unit exceeds its carrying amount, including goodwill. In performing the qualitative assessment, the Company considers certain events and circumstances specific to the reporting unit and to the entity as a whole, such as macroeconomic conditions, industry and market considerations, overall financial performance and cost factors when evaluating whether it is more likely than not that the fair value of the reporting unit exceeds its carrying amount. The Company is also permitted to bypass the qualitative assessment and proceed directly to the quantitative assessment. If the Company chooses to undertake the qualitative assessment and concludes that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the Company would then proceed to the quantitative impairment assessment. In the quantitative assessment, the Company compares the fair value of the reporting unit to its carrying amount, which includes goodwill. If the fair value exceeds the carrying value, no impairment loss exists. If the fair value is less than the carrying amount, a goodwill impairment loss is measured and recorded.

In the fourth quarter of 2025, the Company recorded an impairment loss on intangible assets of $28,700. For additional details regarding goodwill and intangible assets, refer to Note 5.

Series X Convertible Preferred Stock

The Company has classified its Series X convertible preferred stock, referred to as Series X Preferred Stock, as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the shares in cash upon certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company as holders of the Series X Preferred Stock could cause redemption of the shares in these situations. The Company did not accrete the carrying values of the preferred stock to the redemption values since a liquidation event was not considered probable as of December 31, 2025 or December 31, 2024. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur**.**

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including stock-based compensation and benefits, facilities costs, costs of clinical trials, sponsored research, manufacturing, and external costs of outside vendors engaged to conduct preclinical development activities and trials.

Costs incurred in obtaining technology licenses are immediately recognized as research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities, and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, stock-based compensation, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, preclinical and clinical development activities, and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are expensed in the period in which they are incurred in the consolidated statements of operations and comprehensive loss.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors and non-employee consultants based on the fair value on the date of the grant and recognizes compensation expense of those awards, net of forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The Company applies the straight-line method of expense recognition to all awards with only service-based vesting conditions and applies the graded vesting method to all awards with performance-based vesting conditions or both service-based and performance-based vesting conditions.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. The Company accounts for forfeitures as they occur. For performance-based awards, the Company does not recognize expense until the underlying vesting conditions are deemed to be probable of occurrence.

The Company classifies share-based compensation expenses in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified, either to general and administrative expenses or research and development expenses.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company estimates its expected stock volatility using a combination of its own historical stock price volatility and the historical volatilities of a group of peer companies in its industry with similar market characteristics. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods

approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The quoted market price of the Company's common stock is used to estimate the fair value of the stock-based awards at grant date.

Income Taxes

The Company accounts for income taxes using 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 recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Inflation Reduction Act of 2022

On August 16, 2022, the Inflation Reduction Act of 2022, or IR Act, was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of the Treasury, or Treasury, has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

Any redemption or other repurchase that occurs after December 31, 2022, in connection with a business combination, extension vote or otherwise, may be subject to the excise tax. Whether and to what extent the Company would be subject to the excise tax in connection with a business combination, extension vote or otherwise would depend on a number of factors, including (i) the fair market value of the redemptions and repurchases in connection with the business combination, extension or otherwise, (ii) the structure of a business combination, (iii) the nature and amount of any private investment in public equity, or the PIPE, or other equity issuances in connection with a business combination (or otherwise issued not in connection with a business combination but issued within the same taxable year of a business combination) and (iv) the content of regulations and other guidance from the Treasury. In addition, because the excise tax would be payable by the Company and not by the redeeming holder, the mechanics of any required payment of the excise tax have not been determined. The foregoing could cause a reduction in the cash available on hand to complete a business combination and in the Company's ability to complete a business combination.

Segment reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or CODM, in deciding how to allocate resources and in assessing performance. The Company's CODM is its Chief Executive Officer, or CEO. The Company operates and manages its business as a single operating and reportable segment on a consolidated basis, which is consistent with how its CODM reviews financial performance and allocates resources.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's other comprehensive loss in all periods presented includes unrealized gains (losses) on available-for-sale investments and foreign currency translation adjustments.

Net Loss per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting loss per share attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, Series X non-voting convertible preferred stock, outstanding options and warrants to purchase common stock are considered potentially dilutive securities.

Recently Adopted Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-04, *Debt—Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, to improve relevance and consistency in application of the induced conversion guidance in Subtopic 470-20. The ASU 2024-04 is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted as of the beginning of the annual reporting period for all entities that have adopted the amendments in ASU 2020-06, *Debt—Debt with Conversion and Other Options and Derivatives and Hedging—Contracts in Entity's Own Equity: Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-02, *Codification Improvements—Amendments to Remove References to the Concepts Statements*, that contains amendments to the Codification that remove references to various FASB Concepts Statements. This effort facilitates Codification updates for technical corrections such as conforming amendments, clarifications to guidance, simplifications to wording or the structure of guidance, and other minor improvements. Adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In March 2024, the FASB issued ASU 2024-01, *Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards*, to improve GAAP by adding an illustrative example that includes four fact patterns to demonstrate how an entity should apply the scope guidance in paragraph 718-10-15-3 to determine whether a profits interest award should be accounted for in accordance with Topic 718, *Compensation—Stock Compensation*. For public business entities, the amendments in this ASU are effective for annual periods beginning after December 15, 2024. Adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures by requiring disaggregated information about an entity's effective tax rate reconciliation, as well as information on taxes paid. This ASU is effective for annual periods beginning after December 15, 2024. The Company has adopted this ASU prospectively for the year ended December 31, 2025 and prepared the required disclosures, refer to Note 14.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Segment Disclosures*, to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This ASU is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. On January 1, 2023, the Company adopted this ASU. The Company has evaluated the impact of the new requirements and prepared the required disclosures. Refer to Note 2 for the Company's segment reporting accounting policy and Note 13 for a summary of the segment loss, including significant segment expenses.

Accounting Pronouncements Not Yet Adopted

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*. The amendments include technical corrections, clarifications, and minor improvements to various Topics within the FASB ASC. The ASU is effective for annual reporting periods beginning after December 15, 2026, and interim periods within those annual reporting periods, with early adoption permitted. Adoption of this guidance is not expected to have a material impact on the Company’s consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. The amendments clarify the application of interim reporting guidance, including when Topic 270 applies, and improve the consistency and usefulness of interim disclosures. The amendments are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, for public business entities and for interim reporting periods within annual reporting periods beginning after December 15, 2028, for entities other than public business entities. Early adoption is permitted for all entities. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In January 2025, the FASB issued ASU 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*, to clarify the effective date of ASU 2024-03, Income Statement—Reporting Comprehensive Income: Disaggregation of Income Statement Expenses. FASB clarified that all public business entities should initially adopt the disclosure requirements in the ASU 2024-03 in the first annual reporting period beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income (Topic 220): Disaggregation of Income Statement Expenses*, to enhance the transparency and decision usefulness of financial information presented in the income statement by requiring disaggregated information about certain income statement expense line items. The amendments apply to all public business entities. This ASU is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

3. Fair Value of Financial Assets

The following tables present information about the Company’s assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 3,130	$ —	$ —	$ 3,130
Treasury bills	4	—	—	4
	$ 3,134	$ —	$ —	$ 3,134

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 2,539	$ —	$ —	$ 2,539
Treasury bills	8,341	—	—	8,341
	$ 10,880	$ —	$ —	$ 10,880

During the years ended December 31, 2025 and 2024, there were no transfers between levels.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2025	December 31, 2024
Prepaid research and development	$ 230	$ 116
Other current assets	881	676
Total prepaid expenses and other current assets	$ 1,111	$ 792

5. Goodwill and Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets and goodwill are tested for impairment at least annually. The assessment of recoverability and impairment was performed at the individual indefinite-lived intangible asset level. The Company incurred impairment loss on indefinite-lived intangible assets of $28,700 and $37,000 for the years ended December 31, 2025 and 2024, respectively, in connection with funding constraints that are causing the delay in further clinical development of LTI-01 and other preclinical programs until additional funds are raised. In the fourth quarter of 2025, the Company decided to pause development activities related to LTI-01 for an indefinite period and focus on the development of LTI-03. The timing and likelihood of resuming development of LTI-01 are uncertain and contingent on the Company's ability to obtain additional financing and the future success of LTI-03. Therefore, the Company wrote off the total carrying value of the LTI-01 asset and other preclinical programs as of December 31, 2025, which resulted in an impairment loss of $28,700 for the year ended December 31, 2025. This impairment charge is classified within impairment loss on intangible assets in the consolidated statements of operations and comprehensive loss. The fair value of intangible assets was determined using multi-period excess earning method and using Level 3 inputs, which included estimates of forecasted cash flows for each candidate. There was no impairment loss recognized for the LTI-03 asset during the year ended December 31, 2025.

The Company performed an impairment assessment of its goodwill, both qualitatively and quantitatively, and concluded that the fair value of goodwill exceeds its carrying value, therefore no goodwill impairment was recognized as of December 31, 2025. The fair value of reporting unit was determined using the income approach with a reconciliation to market capitalization.

Goodwill and indefinite-lived intangible assets consisted of the following:

	December 31, 2025	December 31, 2024
Goodwill	$ 6,330	$ 6,330
Indefinite-lived intangible assets	13,500	42,200
	$ 19,830	$ 48,530

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2025	December 31, 2024
External research and development services	$ 765	$ 2,720
Payroll and payroll-related costs	940	1,474
Professional fees	401	522
Other	98	122
Total accrued expenses and other current liabilities	$ 2,204	$ 4,838

7. Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, par value $0.001 per share. As of December 31, 2025 and December 31, 2024, the Company had issued 24,610 shares of Series X Preferred Stock, of which 12,232 shares of Series X Preferred Stock remained outstanding

At the 2023 annual meeting of stockholders, or the 2023Annual Meeting, the Company's stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of the Company's outstanding Series X Preferred Stock. On March 5, 2024, based upon then existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock. On May 8, 2024, the Bios Entities (as defined below) provided notice to the Company and converted 421 shares of Series X Preferred Stock held by them into 421,000 shares of common stock. As of December 31, 2025 and December 31, 2024, 12,232 shares of Series X Preferred Stock (which are convertible into 12,232,000 shares of common stock) remained convertible at the option of the holder thereof, subject to certain beneficial ownership limitations (as described below).

The Company evaluated the Series X Preferred Stock for liability classification in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, or ASC 480, and determined that equity treatment was appropriate because the Series X Preferred Stock did not meet the definition of the liability instruments. Specifically, the Series X Preferred Stock is not mandatorily redeemable and does not embody an obligation to buy back the shares outside of the Company's control in a manner that could require the transfer of assets. The Company determined that the Series X Preferred Stock would be recorded as temporary equity, based on the guidance of ASC 480, given that it is contingently redeemable.

Each share of Series X Preferred Stock is convertible into 1,000 shares of Common Stock. The preferences, rights, and limitations initially applicable to the Series X Preferred Stock are set forth in the Certificate of Designation of Series X Non-Voting Convertible Preferred Stock, or the Certificate of Designation.

The Series X Preferred Stock has the following characteristics:

Voting

Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or by-laws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Dividends

Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock. Such dividends are not cumulative. Since the Company's inception, no dividends have been declared or paid.

Liquidation, dissolution or winding up

The Series X Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Upon liquidation, dissolution or winding up of the Company, the Series X preferred stockholders shall be entitled to receive an equivalent amount of distributions as would be paid on the common stock underlying the Series X Preferred Stock, determined on an as-converted basis, pari passu with any distributions to the common stock shareholders.

Conversion

The Series X Preferred Stock is convertible into common stock at a rate of 1,000 shares of common stock for every one share of Series X Preferred Stock that is converted. The Series X Preferred Stock is subject to certain beneficial ownership limitations, including that a holder of Series X Preferred Stock is prohibited from converting shares of Series X Preferred Stock into shares of common stock if, as a result of such conversion, such holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates) would beneficially own more than a specified percentage (to be initially set at 19.99% and thereafter adjusted by the holder to a number not to exceed 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Redemption

Shares of the Series X Preferred Stock are not redeemable at the election of the holder.

Maturity

The Series X Preferred Stock shall be perpetual unless converted.

8. Common Stock

As of December 31, 2025 and December 31, 2024, the Company was authorized to issue 100,000,000 shares of common stock, par value $0.001 per share.

As of December 31, 2025 and December 31, 2024, the Company had 27,550,222 and 21,666,012 shares of common stock issued and outstanding, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's Board, if any. As of December 31, 2025 and 2024, no dividends had been declared.

In the event of liquidation or dissolution, the holders of the common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Issuance of Common Stock and Warrants

Wainwright Sales Agreement

On May 15, 2025, the Company entered into the Wainwright Sales Agreement with H.C. Wainwright, as agent and/or principal, pursuant to which the Company could offer and sell shares of its common stock having an aggregate offering price of up to $13,702 from time to time through or to H.C. Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of December 31, 2025, the Company had issued and sold 999,967 shares of common stock pursuant to the Wainwright Sales Agreement for total net proceeds of $1,489, after deducting transaction fees of $52 paid by the Company. In July 2025, in connection with the Yorkville Transactions, the Company reduced the aggregate offering price of the shares of common stock that could be offered and sold under the Wainwright Sales Agreement to $8,067.

Prior to entering into the Wainwright Sales Agreement, in May 2025, the Company terminated its "at the market offering" pursuant to the Equity Distribution Agreement with Citizens JMP. Through May 2025, the Company issued and sold 317,772 shares of common stock pursuant to the Equity Distribution Agreement for total net proceeds of $712, after deducting transaction fees of $22 paid by the Company. The Company did not issue or sell any other shares of common stock pursuant to the Equity Distribution Agreement during the year ended December 31, 2025. The Company did not sell any shares of common stock pursuant to the Equity Distribution Agreement during the year ended December 31, 2024.

Warrant Exercises and Exchanges

On April 21, 2025, the Company entered into privately negotiated letter agreements with certain holders of its outstanding warrants issued on November 2, 2023, or the PIPE Warrants, and May 1, 2024, or the Offering Warrants. Pursuant to these agreements, certain holders agreed to exercise the PIPE Warrants for an aggregate of 159,500 shares of the Company's common stock and the Offering Warrants for an aggregate of 890,138 shares of common stock, at a reduced exercise price of $1.60 per share. The original exercise prices were $4.89 per share for the PIPE Warrants and $4.68 per share for the Offering Warrants. The exercise of the PIPE Warrants was completed on April 24, 2025, and the exercise of the Offering Warrants was completed in May 2025 (collectively, the "Warrant Exercises"). The Company received total net proceeds of $1,595 from the Warrant Exercises.

Separately, in April 2025, the Company entered into agreements with additional holders of the PIPE Warrants who agreed to surrender warrants representing an aggregate of 1,939,000 shares of common stock for cancellation. In exchange, these holders received pre-funded warrants (the "Exchange Pre-Funded Warrants") exercisable for the same number of shares at an exercise price of $0.001 per share and paid $1.599 per share in cash by April 24, 2025 (the "Warrant Exchanges"). The Company received total net proceeds of $2,984 from the Warrant Exchanges.

As part of the Warrant Exchanges, entities affiliated with Bios Equity Partners, LP ("Bios Partners") surrendered PIPE Warrants representing an aggregate of 1,300,500 shares and provided the associated cash consideration of $2,079 for the issuance of Exchange Pre-Funded Warrants.

In addition, on April 21, 2025, an entity affiliated with Bios Partners agreed to purchase additional pre-funded warrants to acquire 312,695 shares of the Company's common stock in a private placement at a price of $1.599 per share, resulting in total net proceeds of $481 (the "Bios Pre-Funded Warrants"). The Exchange Pre-Funded Warrants and the Bios Pre-Funded Warrants are collectively referred to as the "Pre-Funded Warrants."

The Company assessed the Pre-Funded Warrants for appropriate classification under U.S. GAAP and determined that they are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815, *Derivatives and Hedging*. The Pre-Funded Warrants are indexed to the Company's common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the Pre-Funded Warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The Pre-Funded Warrants were initially recognized at their fair value, calculated as the fair value of the underlying common stock less the exercise price of $0.001 per share. The fair value of the common stock was determined based on the quoted market price of the Company's common stock as of the issuance date. The Pre-Funded Warrants will not be remeasured subsequent to initial recognition.

The repricing of the PIPE Warrants and the Offering Warrants and issuance of the Exchange Pre-Funded Warrants is considered a modification under the guidance of ASU 2021-04. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holder to cash exercise their warrants, resulting in the imminent exercise of the PIPE Warrants and the Offering Warrants, which raised equity capital and generated net proceeds for the Company of approximately $4,601. The total fair value of the consideration of the modification includes the incremental fair value of the PIPE Warrants and the Offering Warrants (determined by comparing the fair values immediately prior to and immediately after the modification) and the initial fair value of the PIPE Warrants and the Offering Warrants. The fair values of the PIPE Warrants and the Offering Warrants were calculated using the Black-Scholes model. The Company determined that the total fair value of the consideration related to the modification of PIPE Warrants and the Offering Warrants, including the initial fair value of the Exchange Pre-Funded Warrants was $4,757. The net effect of the modification in the amount of $490, as well as the value of the replaced PIPE warrants of $1,385 and the fair value of the Exchange Pre-Funded Warrants of $5,652 were recorded in additional paid-in capital, as both the original warrants (the PIPE Warrants and the Offering Warrants) and the replacement instruments (the Exchange Pre-Funded Warrants) are equity-classified.

The Offering Warrants

In May 2024, the Company completed the Offering pursuant to which the Company issued and sold 4,273,505 shares of the Company's common stock and accompanying the Offering Warrants to purchase 4,273,505 shares of common stock. All of the Offering Shares and the Offering Warrants were sold by the Company. Each Offering Share was offered and sold together with an accompanying Offering Warrant at a combined public offering price of $4.68, and the underwriter purchased each Offering Share and accompanying Offering Warrant from the Company, after the underwriting discount, at a combined price of $4.35. Net proceeds from the Offering were approximately $17,675,

after deducting underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the Offering Warrants. The Offering closed on May 3, 2024.

Each Offering Warrant has an exercise price per share of common stock equal to $4.68. Each Offering Warrant may be exercised until May 1, 2027. Each Offering Warrant is exercisable solely by means of a cash exercise, except that an Offering Warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of Offering Warrant Shares is not then effective or the prospectus contained therein is not available for the issuance of Offering Warrant Shares.

The Offering Warrants include certain rights upon "fundamental transactions" as described in the Offering Warrants, including the right of the holders thereof to receive from the Company or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction (as described in such Offering Warrants) of the unexercised portion of the applicable Warrants immediately prior to such fundamental transaction. A holder of Offering Warrants (together with its affiliates) may not exercise any portion of an Offering Warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding common stock immediately after exercise.

The Company had assessed the Offering Warrants for appropriate equity or liability classification and determined the Offering Warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815. The Offering Warrants are indexed to the Company's common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the Offering Warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The Offering Warrants were initially recognized at their relative fair value in the amount of $8.0 million at the time of issuance determined using Black-Scholes option-pricing model and will not be remeasured.

The following assumptions were used to perform the Offering Warrants valuation:

		May 3, 2024
Risk-free interest rate		4.6%
Expected term (in years)		3.0
Expected volatility		113.5%
Expected dividend yield		0%
Stock price	$	3.76
Exercise price	$	4.68

The Offering Warrants to purchase 884,798 shares of common stock were exercised in April 2025 as part of April 2025 Transactions. As of December 31, 2025, Offering Warrants to purchase 3,388,707 shares of common stock remained outstanding.

Prepaid Purchase Agreement

On July 29, 2025, the Company entered into a PPA with Yorkville, pursuant to which the Company may request pre-paid advances of up to $6,000 from Yorkville over a 12-month period, subject to certain limitations and conditions set forth in the PPA. Each Pre-Paid Advance is subject to the consent of Yorkville. Interest shall accrue on the outstanding balance of any Pre-Paid Advance at an annual rate of 8%, subject to an increase to 18% upon events of default described in the PPA. All Pre-Paid Advances are due and payable on the 12-month anniversary of their issuance. At any time that there is an outstanding balance under any Pre-Paid Advances, Yorkville may provide written notice, or Purchase Notice, requiring the Company to issue and sell shares of its common stock to Yorkville, which shall be offset against and reduce the amounts outstanding under the Pre-Paid Advance. The initial advance under the PPA of $1,000 was purchased on July 29, 2025, with net proceeds of $950 after a 5% original issue discount, or OID. On September 8, 2025, the Company entered into a second PPA with Yorkville for an additional $1,000 advance, with net proceeds of $950 after the 5% OID. On October 23, 2025, the Company entered into a third PPA with Yorkville for an additional $1,000 advance, with net proceeds of $950 after the 5% OID.

The Company elected the fair value option under ASC 825, *Financial Instruments*, or ASC 825, to measure the PPAs at fair value, with changes in fair value recognized in earnings. The initial fair value was determined to be equal to the net proceeds received ($950 per PPA), as this amount represented the cash consideration exchanged, consistent with ASC 825. OID costs of $100 related to the first and second PPA were expensed as incurred in the third quarter of 2025, as required under the fair value option. Additionally, the Company incurred legal costs of $118 which were expensed in the consolidated statements of operations and other comprehensive loss.

Under the terms of the PPAs, the Company issued shares of common stock to Yorkville in satisfaction of the advances. The number of shares issued was determined based on the applicable purchase price per share equal to the lower of (a) 115% of the daily volume weighted average price, or the VWAP, of the Company's common stock on the last full trading day immediately prior to the date of such Pre-Paid Advance and (b) 95% of the lowest daily VWAP of the Company's common stock during the seven consecutive trading days immediately preceding the date on which Yorkville provides the Purchase Notice to the Company, but in no event less than the floor price set forth in the PPA. The carrying value of the PPA and accrued interest were reduced by the issuance of the shares.

Under the terms of the PPAs, through September 24, 2025, the Company issued an aggregate of 1,880,872 shares of common stock to Yorkville (953,765 shares under the first PPA through September 9, 2025, and 927,107 shares under the second PPA), based on the principal of $2,000 from the PPA and $11 of interest expense. The shares were recorded at par value of $0.001 per share with the remainder credited to additional paid-in capital, or APIC.

On October 23, 2025, Yorkville purchased a third PPA of $1,000, for which the Company received net proceeds of $950. The third PPA was converted to 846,290 shares of the Company's common stock in October 2025, with no remaining outstanding balance. The shares were recorded at par value of $0.001 per share with the remainder credited to APIC.

The initial, the second and the third PPAs were fully settled as of December 31, 2025, with no remaining outstanding balance. Accordingly, the fair value of the liabilities at December 31, 2025, was $0, and no adjustment for changes in fair value was required.

On December 11, 2025, the Company terminated the PPA.

Standby Equity Purchase Agreement

On July 29, 2025, the Company entered into a SEPA with Yorkville. Under the SEPA, the Company has the right to sell to Yorkville up to $15.0 million of its common stock, par value $0.001 per share, subject to certain limitations and conditions set forth in the SEPA, from time to time, over a 36-month period.

The Company did not issue any SEPA Advances during the year ended December 31, 2025. On December 11, 2025, the Company terminated the SEPA.

At the 2023 Annual Meeting, the Company's stockholders also approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of the Company's outstanding Series X Preferred Stock. On March 5, 2024, based upon then existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock.

As of December 31, 2025, there were:

- 12,469,000 shares of common stock reserved for issuance upon conversion of the Series X Preferred Stock;
- 3,143,997 shares of common stock issuable upon the exercise of options under existing equity incentive plans;
- 420,000 shares of common stock issuable for vested but unsettled restricted stock units (Note 10);
- 1,914,194 and 7,500 shares of common stock reserved for issuance under the 2021 Plan (Note 10) and 2017 ESPP (Note 10), respectively, as well as any automatic increases in the number of shares of the common stock reserved under these plans; and

- 6,621,839 shares of common stock reserved for issuance upon exercise of outstanding warrants. The warrants consist of (i) warrants to purchase 726,437 shares of the Company's common stock, with an exercise price of $5.66, which expire on May 20, 2029, which were assumed in connection with the Lung Acquisition, (ii) warrants to purchase 255,000 shares of the Company's common stock, with an exercise price of $4.89 per share, which were issued and sold in the PIPE Financing as described above and expire on May 2, 2027, (iii) warrants to purchase 3,388,707 shares of the Company's common stock, with an exercise price of $4.68 per share, which were issued and sold in the Offering as described above and expire on May 3, 2027, (iv) the Exchange Pre-Funded Warrants to purchase 1,939,000 shares of the Company's common stock, with an exercise price of $0.001 per share, which were issued and sold in the Warrant Exchanges as described above can be exercised at any time after their original issuance until such Exchange Pre-Funded Warrants are exercised in full, and (v) the Bios Pre-Funded Warrants to purchase 312,695 shares of the Company's common stock, with an exercise price of $0.001 per share, which were issued and sold in April 2025 as described above and can be exercised at any time after their original issuance until such Bios Pre-Funded Warrants are exercised in full.

Accordingly, as of December 31, 2025, out of the 100,000,000 shares of common stock presently authorized, 52,126,752 shares are issued and outstanding or reserved for issuance and 47,843,248 shares of common stock remain available for future issuance.

9. Compensation

The Company has a 401(k) plan available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. The Company provides an employer match, which is 100% of employee deferrals up to the first 3% of compensation for the period and 50% of the next 2% of compensation for the period and is immediately vested. The Company made matching contributions in the amount of $99 and $101 for the years ended December 31, 2025 and 2024, respectively.

10. Stock-Based Awards

As of December 31, 2025, the Company had five equity compensation plans, each of which was approved by its stockholders: 2006 Equity Incentive Plan, as amended, or the 2006 Plan, 2016 Stock Incentive Plan, or the 2016 Plan, 2017 Stock Incentive Plan, or the 2017 Plan, 2021 Stock Incentive Plan, or the 2021 Plan, and 2017 Employee Stock Purchase Plan, or the 2017 ESPP. The Company also assumed Lung's 2013 Long-Term Incentive Plan, or the 2013 Plan, as a result of the Lung Acquisition.

As of December 31, 2025, the Company had no shares issuable upon exercise of outstanding options under the 2006 Plan; 8,404 shares to be issued upon exercise of outstanding options under the 2016 Plan, 98,528 shares to be issued upon exercise of outstanding options under the 2017 Plan and 1,520,179 shares to be issued upon exercise of outstanding options under the 2021 Plan. No shares remained available for future awards under the 2006 Plan, the 2016 Plan, and the 2017 Plan as of December 31, 2025. Shares that are expired, terminated, surrendered or canceled without having been fully exercised under the 2017 Plan will be available for future awards under the 2021 Plan. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards under the 2021 Plan.

Under the 2021 Plan, shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

The exercise price for stock options granted may not be less than the fair market value of the common stock as of the date of grant.

2021 Stock Incentive Plan

The Company's 2021 Plan was approved by the Company's stockholders on June 15, 2021 and became effective on June 16, 2021. At the 2023 Annual Meeting, the stockholders of the Company approved an amendment, or the Plan Amendment, to the 2021 Plan to increase the number of shares of common stock issuable under the 2021 Plan

by 3,000,000 shares to 3,840,254. Other than increasing the number of shares issuable under the 2021 Plan, the Plan Amendment does not make any changes to the 2021 Plan.

Under the 2021 Plan, the Company may grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, awards of restricted stock units and other stock-based awards. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan; however, incentive stock options may only be granted to employees. The 2021 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The number of shares of common stock covered by options and the date those options become exercisable, type of options to be granted, exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated.

Stock options granted under the 2021 Plan with service-based vesting conditions generally vest over four years and may not have a duration in excess of ten years, although options have been granted with vesting terms of less than four years.

The total number of shares of common stock that may be issued under the 2021 Plan was 3,840,254 as of December 31, 2025, of which 1,914,194 shares remained available for grant. The Company initially reserved 625,000 shares of common stock, plus the number of shares of common stock subject to outstanding awards under the 2017 Plan, the 2016 Plan and the 2006 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right up to 314,006 shares. As of December 31, 2025, the Company had 1,520,179 shares to be issued upon exercise of outstanding options under the 2021 Plan.

2013 Stock Incentive Plan

The Company assumed the 2013 Plan as a result of the Lung Acquisition. In October 2013, Lung's Board of Directors, or the Lung Board, approved the 2013 Plan to provide long-term incentives for its employees, non-employee directors and certain consultants. As of December 31, 2025, 1,516,886 shares were reserved to be issued upon exercise of options outstanding under the 2013 Plan. These options were assumed by the Company in connection with the Lung Acquisition.

Before the Lung Acquisition, the 2013 Plan was administered by the Lung Board or, at the discretion of the Lung Board, by a committee of the Lung Board. The exercise prices, vesting and other restrictions were determined at the discretion of the Lung Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The contractual term for stock option awards is ten years. The vesting periods for equity awards were determined by the Lung Board, but generally were four years. The contractual term for stock option awards is ten years. Following the closing of the Lung Acquisition on October 31, 2023, no further awards can be granted under the 2013 Plan.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of the stock options granted to employees and directors during the year ended December 31, 2025 and 2024 were as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.0%	4.1%
Expected term (in years)	5.5	6.0
Expected volatility	107.1%	111.9%
Expected dividend rate	0%	0%

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2025:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2025	3,169,468	$ 5.41	7.0	$ 1,605
Granted	87,500	1.55	—	—
Exercised	(21,533)	1.05	—	18
Forfeited/Canceled	(59,310)	2.73	—	—
Expired	(32,128)	22.50	—	—
Outstanding at December 31, 2025	3,143,997	$ 5.21	6.1	$ 158
Options exercisable at December 31, 2025	2,418,033	$ 6.00	5.4	$ 138
Options vested and expected to vest at December 31, 2025	3,120,459	$ 5.23	6.1	$ 157
Options exercisable at December 31, 2024	2,059,025	$ 6.79	5.6	$ 1,524
Options vested and expected to vest at December 31, 2024	3,120,812	$ 5.45	7.0	$ 1,600

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2025 was $1.26. The weighted average grant-date fair value of stock options granted during the year ended December 31, 2024 was $2.46. The aggregate fair value of stock options that vested during the year ended December 31, 2025 and 2024, was $1,025 and $1,520, 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 exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2025 and 2024 was $18 and $354, respectively.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder.

A summary of the restricted stock unit activity during the year ended December 31, 2025 is as follows:

	Restricted Stock Units	Weighted-Average Grant-Date Fair Value, $
Unvested - January 1, 2025	—	$ —
Granted	1,000,000	1.19
Vested	(1,000,000)	1.19
Unvested - December 31, 2025	—	$ —

The fair value of these vested restricted stock units was $1,194 at the grant date and all of the compensation expense was recognized in the year ended December 31, 2025.

On October 30, 2025, and December 2, 2025, the Company issued 300,000 and 280,000 shares of common stock for the restricted stock units granted and vested in August 2025, respectively. As of December 31, 2025, there were 420,000 vested restricted stock units that were not issued.

Stock-Based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted stock units in the following expense categories of its statements of operations and comprehensive loss:

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 187	$ 162
General and administrative expenses	2,037	955
Total stock-based compensation expense	$ 2,224	$ 1,117

As of December 31, 2025, the Company had an aggregate of $1,475 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 2.77 years.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows**:**

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (49,871)	$ (62,883)
Denominator:		
Weighted average common shares outstanding—basic and diluted	25,444,795	17,938,899
Net loss per share attributable to common stockholders—basic and diluted	$ (1.96)	$ (3.51)

As part of the April 2025 Transactions, the Pre-Funded Warrants to purchase an aggregate of 2,251,695 shares of common stock at an exercise price of $0.001 per share are included within the denominator for basic net loss per share purposes and considered outstanding as of the date of issuance.

The 420,000 restricted stock units vested but not issued as of December 31, 2025, are included in earnings per share calculation as all conditions for issuance have been satisfied making the underlying shares contingently issuable and economically equivalent to outstanding shares.

The Company's potential dilutive securities, which include stock options as of December 31, 2025 and 2024, have been excluded from the computation of diluted net loss per share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	3,143,997	3,169,468
Warrants to issue shares of common stock	6,621,839	7,353,442
Series X Preferred Stock issued and outstanding, as converted	12,232,000	12,232,000
Total	21,997,836	22,754,910

12. Commitments and Contingencies

Legal Proceedings

The Company may from time to time be party to litigation arising in the ordinary course of business. As of December 31, 2025, the Company was not party to any legal proceedings and no material legal proceedings are currently pending or, to the Company's knowledge, threatened.

Intellectual Property Licenses

Harvard and Dana-Farber Agreement

In August 2006, the Company entered into an exclusive license agreement with President and Fellows of Harvard College, or Harvard, and Dana-Farber Cancer Institute, or DFCI. The agreement granted the Company an exclusive worldwide license, with the right to sublicense, under specified patents and patent applications to develop, obtain regulatory approval for and commercialize specified product candidates based on cell-permeating peptides. Under the agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize one or more licensed products and to achieve specified milestone events by specified dates. In connection with entering into the agreement, the Company paid an upfront license fee and issued to Harvard and DFCI shares of its common stock.

In February 2010, the agreement was amended and restated, or the Harvard/DFCI agreement, under which additional patent rights were added to the scope of the license agreement and the annual license maintenance fees were increased. Under the Harvard/DFCI agreement, the Company is obligated to make aggregate milestones payments of up to $7,700 per licensed therapeutic product upon the Company's achievement of specified clinical, regulatory and sales milestones with respect to such product and up to $700 per licensed diagnostic product upon the Company's achievement of specified regulatory and sales milestones with respect to such product. In addition, the Company is obligated to pay royalties of low single-digit percentages on annual net sales of licensed products sold by the Company, its affiliates or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis and may be reduced in specified circumstances. In addition, the agreement obligates the Company to pay a percentage, up to the mid-twenties, of fees received by the Company in connection with its sublicense of the licensed products. In accordance with the terms of the agreement, the Company's sublicense payment obligations may be subject to specified reductions.

The Harvard/DFCI agreement requires the Company to pay annual license maintenance fees of $110 each year, which was reduced to $35 starting in 2023. Any payments made in connection with the annual license maintenance fees will be credited against any royalties due.

As of December 31, 2025, the Company had not developed a commercial product using the licensed technologies and no royalties under the agreement had been paid or were due.

Under the Harvard/DFCI agreement, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents and applications in-licensed under the agreement as well as cost reimbursement of amounts incurred for all documented patent-related expenses. The agreement will expire on a product-by-product and country-by-country basis upon the last to expire of any valid patent claim pertaining to licensed products covered under the agreement. The Company incurred $35 license maintenance fees in the year ended December 31, 2025, which was partially reimbursed by Advancium and the remaining is reimbursable by Rients. The Company incurred $35 license maintenance fees in the year ended December 31, 2024.

Agreement with the University of Texas Health Science Center at Tyler

In June 2013, the Company entered into a patent and technology license agreement with UT System, on behalf of UTHSCT. The patent and technology license agreement with UT System, or the UTHSCT Agreement, provides the Company access to patents and technology related to the development of LTI-01 and LTI-03. As part of the UTHSCT Agreement, the Company has (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell certain intellectual property; (ii) a non-exclusive license under the technology rights to manufacture, distribute and sell the licensed product; and (iii) a sublicensing right that allows the Company to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the UTHSCT Agreement. In December 2013, the UTHSCT Agreement was amended and restated to include certain patents in all fields worldwide. In May 2017, the UTHSCT Agreement was amended and restated to modify the specific milestone criteria.

In consideration of the UTHSCT Agreement, the Company agreed to pay past and ongoing patent expenses, and the Company owes UTHSCT sublicensing fees, assignment fees, and single digit royalties on worldwide net product sales, with fixed minimum royalty payments that started in 2015.

Pursuant to the UTHSCT Agreement, the Company is required to use diligent efforts to commercialize the licensed technology as soon as commercially practicable, including maintaining active research and development, regulatory, marketing and sales program, all as commercially reasonable.

The Company may terminate the UTHSCT Agreement for convenience with 90 days' notice. UTHSCT may also terminate the UTHSCT Agreement, but only if the Company breaches the terms of the agreement. The Company did not incur any expense under the UTHSCT Agreement in the years ended December 31, 2025 and 2024.

Agreement with the University of Texas at Austin

In May 2015, the Company entered into a patent license agreement with UT Austin on behalf of UT System. This license agreement with UT Austin, or the UT Austin 6607 Agreement, relates to the patent rights to polypeptide therapeutics and uses thereof. Pursuant to the UT Austin 6607 Agreement the Company has (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell the licensed product; and (ii) a sublicensing right that allows the Company to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. The UT Austin 6607 Agreement was amended and restated in January 2017, November 2018, and June 2019. The amendments related to extension of milestone payment dates and specific terminology around the milestone achievement criteria.

In consideration of the UT Austin 6607 Agreement, the Company agreed to pay past and ongoing patent expenses, milestone fees upon certain development and regulatory milestone events, annual license fees, tiered sublicense fees, assignment fees, low single digit royalties on net sales and a Food and Drug Administration, or FDA, Priority Review Voucher fee if the Company sells or transfers this voucher.

Pursuant to the UT Austin 6607 Agreement, the Company is required to use diligent efforts to commercialize the licensed products, including maintaining active research and development, regulatory, marketing and sales program. Moreover, the Company is required to meet certain development and regulatory milestones by specific dates.

The Company may terminate the UT Austin 6607 Agreement for convenience with 90 days' notice. UT Austin may also terminate the UT Austin 6607 Agreement, but only if the Company breaches the terms of the agreement. The Company did not incur any expense under the UT Austin 6607 Agreement in the years ended December 31, 2025 and 2024.

Agreement with Medical University of South Carolina

In March 2016, the Company entered into a license agreement with Medical University of South Carolina Foundation for Research Development, or MUSC. Pursuant to this license agreement with MUSC, or the MUSC Agreement, the Company has patent rights related to protecting against lung fibrosis by up regulating Cav1. The MUSC Agreement granted (i) a royalty-bearing, exclusive license under the patent rights to make, use and sell the license product; and (ii) a sublicensing right that allows the Company to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. In September 2018, the agreement was amended and restated to include definitions of related methods, related products and related rights.

In consideration of the MUSC Agreement, the Company agreed to pay a non-refundable license fee, patent expenses, milestone fees upon certain development, regulatory and commercial milestone events, sublicense fees, assignment fees and low single digit royalties on net sales, with a fixed minimum royalty payment starting in 2019 and a transaction fee upon the Company's liquidation.

Pursuant to the MUSC Agreement, the Company is required to use diligent efforts to develop, manufacture and sell the licensed products.

The Company may terminate the MUSC Agreement for convenience by providing a written notice to MUSC effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. The Company incurred $25 license fees in the years ended December 31, 2025 and 2024, respectively.

Agreement with Vivarta Therapeutics LLC

In March 2018, the Company entered into a license agreement with Vivarta Therapeutics, LLC, or Vivarta. This license agreement with Vivarta, or the Vivarta Agreement, relates to intellectual property relating to epithelial sodium channel inhibitors and methods to treat pulmonary disease. Pursuant to the Vivarta Agreement the Company has (i) a royalty-bearing, exclusive license under the intellectual property rights to make, use and sell the licensed product, and (ii) a sublicensing right that allows the Company to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement.

In consideration for the Vivarta Agreement, the Company agreed to grant Vivarta a warrant to purchase an aggregate of 75,000 shares of common stock of Lung for $0.12 per share, to pay a license fee of $10,000 upon the

Vivarta Agreement effective date and $40,000 within 30 days of the receipt of a positive freedom to operate analysis from legal counsel. The Company also agreed to pay patent expenses, milestone fees upon certain development and regulatory milestone events, sublicense fees, assignment fees and low single digit royalties on net sales.

Pursuant to the Vivarta Agreement, the Company is required to use diligent efforts to develop, manufacture and sell the licensed products.

The Company may terminate the Vivarta Agreement for convenience by providing a written notice to Vivarta effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. The Company did not incur any expenses under the Vivarta Agreement in the years ended December 31, 2025 and 2024.

Master Services Agreement

In April 2025, the Company entered into a master services agreement with a third party Contract Research Organization, or CRO, under which the CRO has agreed to perform certain services in accordance with written work orders. The work orders set forth the obligations of the parties with regard to conducting the clinical research study entitled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2, Safety, Tolerability and Efficacy Study of Caveolin1-Scaffolding-Protein-Derived Peptide (LTI-03) in Patients with IPF", under the Company's Protocol LTI-03-2001. Pursuant to the agreement, the Company had contracted for up to $17.0 million of master services.

In August 2025, this master services agreement was terminated with no future commitment for the Company.

Exclusive Option Agreement with Advancium

On October 31, 2024, the Company entered into an exclusive option agreement, or the Option Agreement, with Advancium Health Network, or Advancium, for the sale of ALRN-6924, a clinical stage oncology agent that the Company was developing prior to the Lung Acquisition (as defined below). During the option period, Advancium intends to evaluate ALRN-6924 as a potential therapy for retinoblastoma. Under the terms of the option agreement Advancium paid the Company a non-refundable fee of $0.1 million for the exclusive option to acquire ALRN-6924 and related assets. If Advancium exercises its option, the Company will receive an exercise payment with potential for additional development, regulatory and commercial milestone payments and sales royalties.

In July 2025, the Option Agreement was terminated.

Letter Agreement with Rients

In August 2025, the Company entered into a letter agreement with Rients LLC, or Rients, for Rients to evaluate the legacy ALRN-6924 compound, or the Compound Asset. During the term of the letter agreement, Rients shall pay the Company for all fees and expenses incurred by the Company to maintain the Compound Asset.

Project Addendum

In December 2025, the Company entered into a project addendum with a third party CRO for the purposes of setting forth the responsibilities and obligations of the parties in regards to conducting a certain clinical research program entitled "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability and Efficacy of Caveolin-1-Scaffolding-Protein-Derived Peptide in Patients with IPF" under the Company's Protocol LTI-03-2001. Pursuant to the project addendum, the Company had contracted for up to $19.8 million of master services.

Advisory Agreements

The Company has entered into various arrangements with certain business advisors, consultants, and investment institutions to assist the Company with fundraising and to provide certain advisory services. In connection with these arrangements, the Company may be required to pay such business advisors, consultants, and investment institutions certain contingent fees related to their services to the extent that certain conditions are met, such as the successful fundraising. There are no contingent fees payable under these arrangements as of December 31, 2025 or December 31, 2024.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In

addition, the Company has entered into indemnification agreements with members of its board of directors and officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 or December 31, 2024.

13. Segment Reporting

The Company has one reportable segment which focuses on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. The Company's CODM, the CEO, manages the Company's operations on a consolidated basis as one operating segment for the purposes of evaluating financial performance and allocating resources.

The Company has not generated any revenue yet. The CODM assesses the financial performance of the segment and decides how to allocate resources based on net loss on a consolidated basis. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

The CODM uses net loss predominantly in the annual operating budget and in the strategic planning and forecasting process. Such loss measure is used to monitor budget versus actual results on an ongoing basis by the CODM and determine how resources are allocated to the various activities of the Company. The CODM also uses net loss to evaluate the Company's performance and assist in determination of management's incentive compensation.

All of the Company's tangible assets are held in the United States. The Company views its operations and manages its business in one operating segment operating exclusively in the United States.

The table below is a summary of the segment loss, including significant segment expenses:

	Year Ended December 31,	
	2025	2024
Revenues	$ —	$ —
Research and development expenses:		
LTI-01 program-related expenses:		
Preclinical study costs	—	2
CMC activities	1,066	3,566
Clinical operation activities	413	46
Total LTI-01 program-related expenses	1,479	3,614
LTI-03 program-related expenses:		
Preclinical study costs	778	1,935
CMC activities	2,239	2,451
Clinical operation activities	4,285	3,913
Total LTI-03 program-related expenses	7,302	8,299
Other program-related expenses	11	54
Employee related expenses	2,119	2,200
Professional fees for services	44	34
Facilities and other expenses	74	47
Total research and development expenses	11,029	14,248
General and administrative expenses:		
Employee related expenses	3,748	5,465
Professional fees for services	5,191	6,257
Facilities and other expenses	1,963	2,142
Total general and administrative expenses	10,902	13,864
Impairment loss on intangible assets	28,700	37,000
Other income, net	(48)	(685)
Income tax benefit	(712)	(1,544)
Segment and consolidated net loss	$ (49,871)	$ (62,883)

14. Income Taxes

On October 31, 2023, the Company acquired, in accordance with the terms of the Lung Acquisition Agreement, the stock of Lung. In accordance with ASC 805, *Business Combination*, recognition of deferred tax assets and liabilities is required for substantially all temporary differences and acquired tax carryforwards and credits. The Company has computed estimated temporary differences and acquired tax carryforwards and credits as of the transaction date. The Company will not have tax basis in intangible assets recorded as part of the purchase. For accounting purposes, the intangible assets will not be amortized and subject to impairment review and testing. Though the tax effects may be delayed indefinitely, ASC 740, *Accounting for Income Taxes,* states that "deferred tax liabilities may not be eliminated or reduced because a reporting entity may be able to delay the settlement of those liabilities by delaying the events that would cause taxable temporary differences to reverse." As such, the Company has recorded a deferred tax liability for the portion of the liability that cannot be offset with indefinite lived deferred tax assets.

The Company reported an income tax benefit of $712 for the year ended December 31, 2025. The reported amount of income tax expense for the years differs from the amount that would result from applying domestic federal statutory tax rates to pretax losses primarily because of changes in valuation allowance and indefinite lived intangibles.

Income tax benefit consist of the following:

	Year Ended December 31,	
	2025	2024
Current tax (provision) benefit:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current tax (provision) benefit	—	—
Deferred tax (provision) benefit:		
Federal	1,336	1,544
State	(624)	—
Foreign	—	—
Total deferred tax benefit	712	1,544
Total income tax benefit	$ 712	$ 1,544

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Rate	Amount	Rate	Amount
U.S. Federal statutory income tax rate	(21.0)%	$ (10,616)	(21.0)%	$ (13,495)
State and local income taxes, net of federal benefit	1.2	1 619	(1.3)	(840)
Research and development and orphan drug tax credits	(0.2)	(103)	(0.6)	(400)
Nontaxable or nondeductible items	—	3	—	19
Foreign Tax Effects	—	—	—	—
Effects of Cross-Border Tax Laws	—	—	—	—
Changes in Unrecognized Tax Benefits	—	—	—	—
Effect of Changes in Tax Laws or Rates Enacted in the Current Period	—	—	—	—
Change in valuation allowances	17.3	8,724	18.6	11,947
Stock compensation	1.5	737	1.9	1,225
Other reconciling items	(0.2)	(76)	—	—
Effective income tax rate	(1.4)%	$ (712)	(2.4)%	$ (1,544)

Net deferred tax liabilities as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 28,676	$ 17,423
Research and development and orphan drug tax credit carryforwards	8,328	8,226
Capitalized research and development expenses	6,573	10,907
Accrued expenses and reserves	271	340
Stock compensation	508	608
Total deferred tax assets	44,356	37,504
Valuation allowance	(42,129)	(30,454)
Net deferred tax assets	$ 2,227	$ 7,050
Deferred tax liabilities:		
Depreciation and amortization	$ (3,287)	$ (8,822)
Right of use asset	$ —	$ —
Total deferred tax liabilities	$ (3,287)	$ (8,822)
Net deferred tax liability	$ (1,060)	$ (1,772)

The Company owns Lung Therapeutics, LLC, Lung Therapeutics Australia Pty Ltd, and Lung Therapeutics Limited. There is no material foreign activity during the year ended December 31, 2025. There are no foreign tax attributes for the Company as of December 31, 2024 or December 31, 2025, respectively. As such, certain items have not been separately disaggregated in the income tax disclosures, as it was determined that such disaggregation would not be material, consistent with the materiality guidance in ASC 105-10-05-6.

As of December 31, 2025, the Company had net operating loss carryforwards for federal and state purposes of $122,682 and $46,077, respectively. $2,863 of the U.S. federal tax operating loss carryforwards will begin to expire in 2036. Approximately $119,820 of the U.S. federal tax operating losses can be carried forward indefinitely. Of this amount, $44,420 of federal net operating losses came over from the Lung Acquisition, of which $2,863 will begin to expire in 2036 and the remaining $41,557 can be carried forward indefinitely. The state tax operating loss carryforwards expire beginning in 2043. As of December 31, 2025, the Company also had available research and development tax credit carryforwards for federal income tax purposes of $2,528, which begin to expire in 2035. As of December 31, 2025, the Company also had available orphan drug credit carryforwards of $5,800 for federal income tax purposes, which begin to expire in 2039. Of this amount, $2,222 of research and development credit carryforwards and $5,644 of orphan drug credit carryforwards came over from the Lung Acquisition.

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted. The OBBBA amends U.S. tax law including provisions related to domestic research and development expenses and bonus depreciation, among others. Under the OBBBA provisions, effective with tax years beginning on or after January 1, 2025, taxpayers can now immediately expense domestic research and development expenditures as well as accelerate previously capitalized domestic research and development expenditures from 2022-2024. Taxpayers are still required to capitalize and amortize research and development expenditures over 15 years for research conducted abroad. As a result, the Company expensed net $25,277 of research and development expenses for the year ended December 31, 2025 for tax purposes.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. As of December 31, 2023, the Company has wound down its original business operations and entered into a merger in the year, which resulted in a significant shift in ownership. The Company expects to have all prior year net operating losses and tax credits of its legacy business to be completely limited going forward due to the lack of continuation in its legacy business. As such, all prior year net operating losses and tax credits have been written down to zero as of December 31, 2023 through December 31, 2025, respectively. The remaining net operating losses and tax credits as of December 31, 2025 relate to post-merger

activity, as well as acquired attributes as part of the merger. A study has been completed on the Target ownership shifts through December 31, 2023, and multiple ownership changes were determined. As a result, the Company has written down the $1,673 portion of the Target net operating losses expected to expire unutilized and include the $44,420 of remaining net operating losses and $7,638 of federal tax credits as part of its available attributes. As of December 31, 2025, the total federal net operating losses are $122,726 and federal research and development tax credits are $8,328, which could be subject to future limitations under these rules.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's cumulative net losses and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. The Company maintained a full valuation allowance on its net deferred tax assets as of December 31, 2025. Management reevaluates the positive and negative evidence at each reporting period. The increase in the valuation allowance for deferred tax assets during the years ended December 31, 2025 and December 31, 2024 of $11,675 and $11,948, respectively, related primarily to an increase in net operating loss carryforwards. Changes in the valuation allowance were as follows:

	Year Ended December 31,	
	2025	2024
Valuation allowance at beginning of year	$ (30,454)	$ (18,506)
Decreases recorded as a benefit to income tax provision	(11,675)	(11,948)
Valuation allowance at end of year	$ (42,129)	$ (30,454)

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2025 or 2024.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. The major jurisdictions of the Company are federal and Massachusetts. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from 2021 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss. There are no foreign jurisdictions that the Company operates in as of December 31, 2024 or December 31, 2025, respectively.

15. Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were issued. Based upon this review, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

At the Market Offering

Subsequent to the consolidated balance sheet date, the Company continued its "at the market" offering program under the Wainwright Sales Agreement (described in Notes 1 and 8). Through March 26, 2026, the Company issued and sold 296,810 shares of common stock pursuant to the "at the market" offering program for total net proceeds of $354, after deducting transaction fees of $16 paid by the Company.

2026 Bridge Loans

In January 2026 and February 2026, the Company entered into separate securities purchase agreements, or the Purchase Agreements, with three institutional investors pursuant to which we issued and sold to the investors, in a private placement, unsecured promissory notes in the aggregate original principal amount of $5,375, or the Notes. Pursuant to the Purchase Agreements, the Company issued and sold the Notes to the investors for the aggregate purchase price of $4,300, inclusive of an original issue discount of 20%.

The Notes have a stated maturity date of the earlier of (i) the date of the closing of the next issuance and sale of the Company's securities, in a single transaction or series of related transactions, to investors resulting in gross proceeds to the Company of at least $10,000 (exclusive of the Notes proceeds) or (ii) June 30, 2026. The Company's obligations under the Notes are unsecured. There is no interest payable under the promissory notes other than the 20%

original issue discount. The Purchase Agreements contained representations, warranties, covenants and other terms customary for agreements of such nature.

Issuance of Common Stock

In January 2026 and March 2026, the Company issued 192,000 shares of common stock for the restricted stock units granted and vested in August 2025.