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, 2023

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

Aileron 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	**ALRN**	**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, 2023, 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 Global Market was $6,587,576.

As of April 12, 2024, the Registrant has 16,972,512 shares of Common Stock, $0.001 par value per share, outstanding.

Portions of the Registrant's definitive proxy statement for its 2024 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, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Aileron and the other trademarks or service marks of Aileron appearing in this Annual Report on Form 10-K are the property of Aileron. All other trademarks, service marks or other trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K of Aileron Therapeutics Inc. ("Aileron," "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 proxy statement, 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 and LTI-01, including the potential benefits thereof;
- the timing and expectation of the results of the Phase 1b study of LTI-03;
- 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 ongoing and future clinical trials for LTI-03 and LTI-01, 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 possibility that we may be adversely affected by economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of our preclinical studies and early clinical trials may not be replicated in later clinical trials, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all;
- our ability to recognize the anticipated benefits of the Lung Acquisition (as defined herein);
- 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 estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the timing of and our ability to obtain and maintain marketing approvals for LTI-03 and LTI-01;
- 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 product candidates;
- our reliance on third-party manufacturing and supply vendors;
- potential benefits of any future collaboration;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- the impact of affiliated stockholders choosing to act together; and
- our ability to maintain our listing on the Nasdaq Capital Market.

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, or incorporated by reference, in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that 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 on Form 10-K 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 on Form 10-K 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.

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 on Form 10-K for the year ended December 31, 2023. These risks include the following:

Risks Related to Our Business

- Our business is highly dependent on the success of our product candidates, LTI-03 and LTI-01 and any other product candidates that we advance into clinical development. 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. All of our product candidates will require significant additional development before we may be able to seek regulatory approval for and launch a product commercially. 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.

Risks Related to Our Financial Condition

- We will require substantial additional capital to finance our operations. Our cash and cash equivalents are not sufficient to enable us to complete the development and commercialization of LTI-03 and LTI-01. 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.
- There is no guarantee that our acquisition of Lung and its business will increase stockholder value in our company or that we will be able to realize the anticipated benefits of the acquisition.
- 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 and do not expect to achieve or maintain profitability. Even if we are able to develop and commercialize our product candidates, we may never generate revenues that are significant or large enough to achieve profitability.
- We have identified conditions that raise substantial doubt about our ability to continue as a going concern.

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

- 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, LTI-01 or any other product candidates.
- 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.
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.

Risks Related to Marketing Approval, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

- 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.
- 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.
- 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 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.

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.
- We have entered into a collaboration agreement with Taiho Pharmaceutical Co., Ltd., or Taiho, for the development of LTI-01 and may in the future seek to enter into collaborations with third parties for the development and commercialization of other product candidates. If we fail to enter into such collaborations, or our collaborations are not successful, we may be unable to continue development of such product candidates, we would not receive any contemplated milestone payments or royalties, and we could fail to capitalize on the market potential of such product candidates.

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

- 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.
- 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 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.

PART I

Item 1. Business

Overview and Recent Developments

Aileron Therapeutics, Inc. ("Aileron," "we," "us," "our," or the "Company") is 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, and multiple candidates in preclinical development focused on fibrosis indications. Our pipeline includes:

- LTI-03, a peptide, for which we are currently recruiting patients for 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.

Prior to the termination of development of our main product candidate in February 2023 and the acquisition of Lung Therapeutics, Inc. (as described below), our focus was the development of our main product candidate, ALRN-6924, a MDM2/MDMX dual inhibitor that leveraged our proprietary peptide drug technology. Since our inception, we have devoted a substantial portion of our resources to developing our product candidates, including ALRN-6924, developing our proprietary stabilized cell-permeating peptide platform, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations.

Announcement of Exploration of Strategic Alternatives

In February 2023, we announced a review of initial data from our Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer. Based on these findings, we decided to terminate the Phase 1b breast cancer trial and further development of ALRN-6924. We also announced that we were exploring a range of strategic alternatives to maximize shareholder value. We engaged Ladenburg Thalmann & Co., Inc. to act as a strategic advisor for this process. Strategic alternatives that were being evaluated included, but were not limited to, an acquisition, a merger, a business combination, a sale of assets or other transactions. In addition, in February 2023, we determined to reduce our workforce from nine to three full-time employees, which we completed in the second quarter of 2023.

The Lung Acquisition

On October 31, 2023, we acquired Lung Therapeutics, Inc., or Lung, pursuant to an Agreement and Plan of Merger, or the Lung Acquisition Agreement. Following our acquisition of Lung, or the Lung Acquisition, the business conducted by Lung became the business primarily conducted by the Company and we shifted our operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications.

Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, we issued to the stockholders of Lung 344,345 shares of our common stock and 19,903 shares of our newly designated Series X Preferred Stock. Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. In addition, we assumed all Lung stock options and all warrants exercisable for Lung common stock immediately outstanding prior to the closing of the Lung Acquisition, each subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, we entered into a Stock and Warrant Purchase Agreement, or the Purchase Agreement, with a group of accredited investors, or the Investors, led by Bio Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, and including Nantahala Capital, as well as additional undisclosed investors, pursuant to which we issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants to purchase up to an aggregate of 2,353,500 shares of common stock, or the Warrant Shares, for an aggregate purchase price of approximately $18.4 million, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately $1.6 million issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X Preferred Stock, or the Financing, and collectively with the Lung Acquisition, the Transactions. The Financing closed on November 2, 2023.

On February 28, 2024, we held our 2023 annual meeting of stockholders in which our stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of our outstanding Series X Preferred Stock. Following approval of the conversion of outstanding Series X Preferred Stock, the Company had approximately 29,495,512 shares of common stock issued and outstanding on a pro forma basis, which gives effect to the full conversion of the Series X Preferred Stock as of the date of our 2023 annual meeting of stockholders, without regard to beneficial ownership limitations that may limit the ability of certain holders of Series X Preferred Stock to convert such shares to common stock as such time. On March 5, 2024, based upon existing beneficial ownership limitations, 12,087 shares of Series X Preferred Stock were automatically converted into 12,087,000 shares of common stock. The remaining approximately 12,523 shares of Series X Preferred Stock (which are convertible into 12,523,000 shares of common stock) will remain convertible at the option of the holder thereof, subject to certain beneficial ownership limitations.

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 two 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. 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. Two approved drugs, nintedanib and pirfenidone, have been shown to reduce the rate of lung function decline, but unfortunately provide only modest clinical benefit in IPF patients. Neither drug is curative, and significant side effects or intolerance can occur with the use of pirfenidone and nintedanib. 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 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, 24 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, 12 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 are currently recruiting patients for a randomized, double-blind, placebo-controlled, Phase 1b clinical trial of LTI-03 in IPF patients, which is being conducted at 11 centers in the U.S., UK, Belgium, Germany and Australia. Patients in the trial will either receive 5 mg (one 2.5 mg capsule dosed twice daily) of inhaled LTI-03, 10 mg of inhaled LTI-03 (two 2.5 mg capsules dosed twice daily), or placebo in three active dose patients to one placebo patient randomization for 14 days in a total of 24 IPF patients. The trial will evaluate the safety, tolerability and pharmacodynamic biomarker activity of LTI-03. We expect to report top-line data from the Phase 1b clinical trial in the third quarter of 2024.

LTI-01

LTI-01 is a 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 may 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 expect to investigate LTI-01 in an additional Phase 2 dose-ranging, placebo-controlled clinical trial with a lower dose to establish efficacy and safety.

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.

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, Novartis AG, and Pliant Therapeutics, Inc. 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 two approved branded products for the treatment of IPF; Esbriet, marketed by Roche Holding AG, and Ofev, marketed by Boehringer Ingelheim GmbH. Companies currently developing product candidates in IPF include AbbVie Inc., Boehringer Ingelheim GmbH, Pliant Therapeutics, Inc., Bristol Myers Squibb Company, Avalyn Pharma, Inc., Roche Holding AG, 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 is used off-label to treat LPE. We are not aware of any other pharmaceutical nor 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, Lung 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,

Lung 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 Lung 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, Lung 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 University of Texas Health Science 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 granted UT System (via UTHSCT and UT Horizon Fund affiliates) (i) 2,000,000 shares of Lung common stock and (ii) 400,000 shares of Lung non-convertible preferred stock. On February 6, 2015, UT System exchanged the 400,000 shares of Lung non-convertible preferred stock for 4,000,000 shares of Lung common stock. In addition, Lung agreed to pay past and ongoing patent expenses, and we owe 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.

Agreement with the University of Texas at Austin

In May 2015, Lung entered into a patent license agreement with UT Austin on behalf of the 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, Lung 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 an FDA Priority Review Voucher fee if we sell or transfer 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.

Agreement with Medical University of South Carolina

In March 2016, Lung 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, Lung 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.

Agreement with Vivarta Therapeutics LLC

In March 2018, Lung 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 for the Vivarta Agreement, Lung agreed to grant Vivarta a warrant to purchase an aggregate of 75,000 shares of Lung common stock 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. Lung 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.

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.

Prior to the Lung Acquisition in October 2023, we developed our global patent property portfolio covering the composition of matter of ALRN-6924, its methods of use, and related technology. As described above, we terminated the development of ALRN-6924 in February 2023.

As a result of the Lung Acquisition, as of March 5, 2024, we own or have licensed thirty-three issued patents and forty-one pending patent applications worldwide, two pending international Patent Cooperation Treaty, or PCT, patent applications and one U.S. provisional patent applications, which are material to the programs described below relating to the Lung business. Thirty-one issued patents worldwide and eight pending patent applications are owned by the UT System, which have granted us exclusive license rights to the technology. We own eleven 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 peptides and compositions related to LTI-03 and Cav1-related peptides, methods for therapeutic use of peptides and conjugates of interest and diagnostic methods with peptides of interest 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 5, 2024, we owned two pending PCT applications, eight pending U.S. patent applications including one pending U.S. provisional applications, and fifteen pending applications outside of the U.S. related to the LTI-03 program. We also have licensed: five U.S. patents, including U.S. Patent Nos. 8,697,840, 9,630,990, 10,377,796, 11,161,875, and 11,780,879, twenty-five patents granted outside of the U.S., two pending U.S. application, and six

pending applications outside of the U.S. related to the LTI-03 program. The issued LTI-03 related patents are expected to expire in 2030 or 2034, 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 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 formulations, as well as therapeutic uses of LTI-03 for other indications interest and diagnostic methods.

LTI-01 Program

As of March 5, 2024, we have a license to one U.S. patent from the UT System directed to methods of using intrapleural scuPA polypeptide for decreasing the severity of pleural scarring, which is expected to expire in 2024 without patent term extension.

We expect LTI-01 to be the first to file Biologics License Application, or BLA, in the U.S., which provides for the potential of 12 years exclusivity. The drug is made using a complex process which would likely be difficult to duplicate. In addition, we have received Orphan Drug Designation for pleural empyema in both the U.S. and the EU, which designation should provide exclusivity of seven and ten years, respectively. We believe that, if the product is approved, these designations may afford us exclusivity and the complex production of LTI-01 will provide for additional barriers to entry for potential competition.

U.S. Government Regulation of Drug and Biological Products

In the U.S., FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and in the case of biologics, also under the Public Health Service Act (PHSA) and their implementing regulations. Failure to comply with the applicable U.S. requirements may result in FDA refusal to approve a new drug application (NDA) or a Biologics License Application (BLA). Further, non-compliance may delay product development and could subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, or other corrective action. This could include product seizures, import alerts, total or partial suspension of production or distribution, injunctions and/or civil or criminal prosecution brought by FDA, with the assistance of the U.S. Department of Justice or other governmental entities.

FDA must approve our product candidates for therapeutic indications before they may be marketed in the U.S. For drug products, FDA must approve an NDA, and for biologic products, FDA must approve a BLA. An applicant seeking approval to market and distribute a new drug or biologic in the U.S. generally must satisfactorily complete each of the following steps, where applicable:

- completion of preclinical laboratory tests and animal studies according to good laboratory practices (GLP) regulations or other applicable regulations;
- manufacture and testing of the therapeutic or biologic moiety and its respective product formulation according to good manufacturing practices (cGMP), regulations or other applicable regulations;
- submission to FDA of an investigational new drug application (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 (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 (GCPs) and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to FDA of an NDA or BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;
- 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
- FDA review and approval of the NDA or BLA, which may be subject to additional post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS) and any other potential post-approval studies required by 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 FDA as part of the IND.

An IND is a request for authorization from 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 FDA does not raise concerns within 30 days, it could place the clinical trial on a clinical hold due to potential safety concerns. In such a case, the IND sponsor and 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 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 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.

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 safety monitoring board or committee. 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. 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 FDA, would cause suspension of an ongoing trial until all outstanding concerns have been adequately addressed and 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 FDA's accelerated approval regulations and generate additional safety data regarding use of the product in a clinical setting. In certain instances, 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.

FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or, if the drug has been associated with unexpected serious harm to patients.

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.

During the development of a new drug or biological product, sponsors have the opportunity to meet with 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 FDA to provide advice on the next phase of development.

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 (CMC)) and the proposed labeling are submitted to 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 intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, FDA must find the data submitted to be sufficient to establish the safety and efficacy of the investigational product for its proposed indication. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act (PDUFA), is substantial (for example, for fiscal year 2024 this application fee is approximately $4 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, which is currently more than $400,000 per 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.

FDA conducts a validation of all NDAs and BLAs within 60 days of receipt and informs the sponsor by the 74th day after FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. 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 FDA accepts it for filing.

After the submission is accepted for filing, FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by FDA under PDUFA, 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 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 FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an NDA or BLA to extend beyond the PDUFA goal date.

Before approving an NDA or BLA, 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. 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. 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 FDA.

Additionally, 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. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. 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 FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS and FDA will not approve the NDA or BLA without a REMS.

Under the Pediatric Research Equity Act of 2003 (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 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. FDA must then review the information submitted, consult with the sponsor, and agree upon a final plan. 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 by FDA.

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 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, FDA may issue either an approval letter or a Complete Response Letter (CRL). It could also issue a Refuse to File letter that, in its current state, the NDA or BLA is insufficient to initiate an FDA review. 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 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 FDA's satisfaction in a resubmission of the NDA or BLA, FDA will issue an approval letter. 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, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, FDA may require that contraindications, warnings, or precautions be included in the product labeling (including specific safety-related label warnings). 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. 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 FDA review and approval.

Expedited Programs for Serious Conditions

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, 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 FDA review team to expedite development and review of the product. 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 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 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 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 FDA if the designation is no longer supported. Breakthrough Therapy Designation does not guarantee product approval.

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. 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 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, 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. 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, 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 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 FDA unless FDA informs the applicant otherwise.

Post Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by 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 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. 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 FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional clinical trials and preclinical studies. 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.

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 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.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations, including requirements for quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with FDA and certain state agencies and are subject to periodic unannounced inspections by FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by FDA and other regulatory agencies may identify compliance issues at the facilities of our Contract Manufacturing Organizations that may disrupt production or distribution, or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including voluntary recall and regulatory sanctions as described below.

Once an approval of a drug/biologic product is granted, 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 FDA to approve pending NDAs/BLAs or supplements to approved NDAs/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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (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 (DSCSA) imposes requirements related to identifying and tracing certain prescription drugs distributed in the U.S., including most biological products.

U.S. Patent Term Restoration and Hatch-Waxman Marketing Exclusivity

Depending upon the timing, duration and specifics of 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 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 FDA, reviews and approves the application for any patent term extension or restoration. Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing 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 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, 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. An applicant may also submit a full 505(b)(1) NDA.

The FDCA also provides three years of 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 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 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.

In addition, both drugs and biologics can obtain pediatric exclusivity in the U.S. pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms (it is not a patent term extension itself). This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

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 (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, FDA has approved a number of biosimilars. FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an application 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 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. Upon licensure by FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the U.S.

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. 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 is complex and only beginning to be interpreted and implemented by FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

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

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 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.

The United Kingdom is no longer part of the European Single Market and European Union Customs Union. Though a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, there

are some significant changes made to the regulatory framework to address the United Kingdom's departure from the EU.

The Medicines and Healthcare products Regulatory Agency, or the MHRA, is the national regulator responsible for supervising medicines and medical devices in the United Kingdom, comprising England, Scotland, Wales and Northern Ireland. England, Scotland and Wales form Great Britain which follows domestic law, whereas Northern Ireland currently continues to be subject to European Union rules under the Northern Ireland Protocol. The main domestic legislation regulating medicines in the UK is the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR. The HMR has incorporated into domestic law some of the body of European Union law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union and has been amended to take into account the country's departure from the EU. Other domestic law implements the other corpus of EU medicines law that existed prior to the UK's departure from the EU.

Following Brexit, national marketing authorizations in the UK can be obtained to cover the whole of the UK (UKMA(UK)), Great Britain (UKMA(GB)) or Northern Ireland (UKMA(NI)), through the different available marketing authorization routes. Northern Ireland also continues to participate in the EU marketing authorization routes. In this case, the UK for the purpose of Northern Ireland can be a concerned member state (not a reference member state) for medicines going through the decentralized or mutual recognition procedure. Northern Ireland can also be included within the scope of the centralized procedure.

Any marketing authorizations granted by the MHRA under the decentralized or mutual recognition procedure before Brexit became national marketing authorizations covering the whole of the UK. Centrally authorized products were converted to a UKMA(GB) on January 1, 2021 unless the marketing authorization holder informed the MHRA otherwise, and centrally authorized products continued to be recognized in Northern Ireland.

Until December 31, 2023, the European Commission Decision Reliance Procedure (ECDRP) could be used to obtain a UKMA(GB) with the MHRA relying on a decision taken by the European Commission on the approval of a new MA under the centralized procedure. Similarly, the MHRA could grant UKMA(UK) or UKMA(GB) marketing authorizations under the decentralized and mutual recognition reliance procedure (MRDCRP).

From January 1, 2024, the ECDRP is replaced by a new International Recognition Procedure (IRP). The MRDCRP will be incorporated within the IRP. ECDRP and MRDCRP submissions received by the MHRA before January 1, 2024 continue to follow existing procedures, but for ECDRP applications the CHMP positive opinion (but not necessarily the European Commission Decision) should have been received before December 31, 2023. The IRP procedure is open to applicants who have received an authorization for the same product in one of the MHRA's specified Reference Regulators. The current Reference Regulators include (among others) the FDA, EMA and the national competent authorities of EU / EEA countries.

The start dates of the data and market exclusivity periods for medicines in the UK will depend on which route it was granted. In respect to orphan drugs, the general position under the HMR is 10 years' orphan market exclusivity awarded from the date of authorization by the MHRA (which can be reduced to six years at the end of the fifth year if the licensing authority is satisfied that the orphan criteria is no longer met). An additional two years may be granted where pediatric data requirements are met. A UK-wide orphan marketing authorization can only be granted in the absence of an active EU designation.

On February 27, 2023, the UK and the EU agreed the Windsor Framework which addresses (among other things) the supply of medicines into Northern Ireland. It provides that medicines must be approved and licensed on a UK-wide basis by the MHRA with the same labelling and packaging across the whole of the UK. The EMA will have no role in the approval of new medicines for Northern Ireland. The arrangement takes effect from January 1, 2025.

Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, with some amendments made to address the United Kingdom's departure from the EU, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and

commercialization of product candidates in the United Kingdom. However, there are new routes to obtaining marketing authorizations available such as the IRP.

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 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 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.

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.

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, a 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 the 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.

Rest of the World Regulation

For other countries outside of the EU 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 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 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 health technology assessment (HTA) was adopted by the European Union. 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 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. and Potential Changes to Health Care Laws

Health care reform has been a significant trend in the U.S. health care industry and elsewhere. In particular, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services. Under the Trump administration, there were efforts to repeal or modify prior health care reform legislation and regulation and to implement new health care reform measures, including measures related to payment for drugs under government health care programs. The Biden administration ceased many of these efforts, but continued others, such as implementing mandatory price transparency for providers and insurance companies. The nature and scope of health care reform in the wake of the 2024 election remains uncertain.

There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical and biologic products. At the state level, individual states 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. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

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 General Data Protection Regulation, (EU) 2016/679, or 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 million or up to two percent of our total worldwide annual revenues, whichever is greater, for certain comparatively minor offenses, or up to €20 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, 2023, we had 15 full-time employees, including a total of five employees with M.D. or Ph.D. degrees. Of these full-time employees, six are engaged in research and development activities and nine 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 pursuant to the Lung Acquisition Agreement, after which time Lung became a wholly owned subsidiary of us. 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.aileronrx.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 the 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 Business

Our business is highly dependent on the success of our product candidates, LTI-03 and LTI-01 and any other product candidates that we advance into clinical development. Our approach to drug discovery and development in the area of fibrotic diseases, with a focus on Cav1-related peptides, is unproven and may not result in marketable products. All of our product candidates will require significant additional development before we may be able to seek regulatory approval for and launch a product commercially. 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 currently have no products that are approved for commercial sale and may never be able to develop marketable products. We have two clinical product candidates, LTI-03 and LTI-01, in early- and mid-stage clinical development, respectively. If either of our clinical product candidates encounter 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 are currently recruiting a Phase 1b dose ranging, placebo-controlled safety and tolerability trial of LTI-03 in IPF patients. We have completed a Phase 1b safety, tolerability and proof of mechanism trial and a Phase 2a dose-ranging, placebo-controlled trial of LTI-01 in loculated pleural effusion, or LPE, patients. We must successfully complete Phase 3 clinical trials prior to obtaining FDA approval of LTI-03 or LTI-01 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 candidates, LTI-03 and LTI-01, or any other product candidates, 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.

Risks Related to Our Financial Condition

We will require substantial additional capital to finance our operations. Our cash and cash equivalents are not sufficient to enable us to complete the development and commercialization of LTI-03 and LTI-01. 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.

Developing biopharmaceutical products, including conducting clinical trials and preclinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned clinical trials of LTI-03 and LTI-01 and any future product candidates that we may develop, seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of December 31, 2023, we had approximately $17.3 million in cash and cash equivalents. Based on our current operating plan, we believe that existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials and preclinical studies for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to finish the clinical trials;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- whether we are able to enter into collaboration agreements and the terms of any such agreements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

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.

There is no guarantee that our acquisition of Lung and its business will increase stockholder value in our company or that we will be able to realize the anticipated benefits of the acquisition.

In October 2023, we acquired Lung and shifted our disease focus from chemoprotection to orphan pulmonary and fibrosis indications. We cannot guarantee that implementing the Lung Acquisition and related transactions and the shift in our disease focus will not impair stockholder value or otherwise adversely affect our business or that we will be able to realize the anticipated benefits of the acquisition. The Lung Acquisition poses significant integration challenges between our business and management teams which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of such acquisition to our stockholders.

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 continue our ongoing clinical trial of LTI-03 in patients with IPF, 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 product candidates. Our approach to the research and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. In addition, one clinical product candidate, LTI-03, is in early clinical development and a second clinical product candidate, LTI-01, is in mid-stage clinical development. Both programs 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 and early 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. Even if we are able to develop and commercialize our product candidates, we may never generate revenues that are significant or large enough to achieve profitability.

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, 2023 and 2022, we reported an operating loss of $16.3 million and $27.6 million, respectively. As of December 31, 2023, we had an accumulated deficit of $288.5 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 clinical product candidates, LTI-03 and LTI-01, and our other product candidates, 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 clinical, chemistry, manufacturing, controls, or 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.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company

and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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 $250,000. 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 United States 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.

We have identified conditions that raise substantial doubt about our ability to continue as a going concern and if we are unable to continue as a going concern, we may have to liquidate, dissolve or seek bankruptcy protection.

We do not believe that our cash and cash equivalents as of the date of this Annual Report on Form 10-K will be sufficient to enable us to fund our current operations for at least twelve months from the date of issuance of the financial statements included in this Annual Report on Form 10-K and have therefore concluded that this circumstance raises substantial doubt about our ability to continue as a going concern. See Note 1 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information on our assessment. We expect that we will continue to generate substantial operating losses for the foreseeable future until we complete development and approval of our product candidates.

Our consolidated financial statements have been prepared assuming that we 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. After the Lung Acquisition, we believe that, based on our current operating plan, our cash and cash equivalents as of December 31, 2023, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024 following the date of this Annual Report on Form 10-K.

Since our inception, we have not generated any revenue from product sales and have never generated an operating profit. We have incurred significant losses on an aggregate basis. 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. In February 2023, we discontinued development of ALRN-6924 which substantially reduced our operating expenses. Notwithstanding these events, we expect to continue to incur operating losses for the foreseeable future unless we complete development and approval of our product candidates. We will continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern as of the date of this Annual Report on Form 10-K. We plan to address these conditions by raising funds from our current investors, potential outside investors and other funding sources. However, there is no assurance that such funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The reaction of investors to the inclusion of a going concern statement by our auditors and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. Our funding estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future viability is dependent on our ability to raise additional capital, enter into a financing, consummate a successful acquisition, merger, business combination, or a sale of assets or other transaction. If we become unable to continue as a going concern, we may have to:

- significantly delay, scale back, or discontinue the development or commercialization of our product candidates;
- seek strategic partnerships, or amend existing partnerships, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements; or
- file for bankruptcy or cease operations altogether (and face any related legal proceedings).

Any of these events could have a material adverse effect on our business, operating results and prospects.

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, 2023. 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. The material weaknesses primarily related to the accounting for the business combination with Lung Therapeutics, Inc., specifically the (i) lack of sufficient accounting and supervisory personnel to maintain appropriate segregation of duties relating to user access of the financial accounting system and who have the appropriate level of technical accounting experience and training, (ii) lack of evidence over reviews of account reconciliations and supporting schedules, and (iii) 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 for additional information regarding the material weaknesses.

We are implementing 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.

If we identify material weaknesses in the future, and we are unable to remediate any such material weaknesses, our reputation, financial reporting and condition, and operating results could suffer. Moreover, we could become subject to investigations by regulatory authorities, which could require additional financial and management resources.

We are required to disclose changes made in our internal control procedures on a quarterly basis. Our management is required to assess the effectiveness of these controls annually. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, for so long as we are neither a "large accelerated filer" nor an "accelerated filer", we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. An independent assessment of the effectiveness of our internal control over financial reporting could detect additional material weaknesses that our management's assessment might not detect. Undetected material weaknesses in our internal control over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

During the course of our review and testing, we may identify additional material weaknesses and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost and timing of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions or pandemics;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of

analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

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 are conducting and 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, LTI-01 or any other product candidates.

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, LTI-01 or any other product candidates, 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. 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 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 and LTI-01 or any of our other product candidates. 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 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 FDA policy during the period of product development and 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 the 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, the law's ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

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. Orphan Drug Designation for LTI-03 for IPF and U.S. and European Union, or 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. 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 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 subsist 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.

Under EU law, the protection of an orphan medicinal product does not only apply to medicinal products with the same active substance, but extends to all "similar medicinal products". This is determined by the molecular structure, the mechanism of action and the approved therapeutic indication. Once an orphan medicinal product has been authorized, the European Commission, the EMA and the national regulatory authorities may not, for a period of ten years from the date of authorization, in respect of such similar medicinal products for the same therapeutic indication: accept another application for authorization, grant a corresponding authorization, or grant an application to extend an existing authorization. Thus, not only market exclusivity is conferred, but also additional protection by prohibiting any application and/or granting of authorization for a similar medicinal product during this 10-year period.

Yet, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition or the FDA or the European Commission can approve a similar drug for a different indication. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective, or makes a major contribution to patient care. In the EU, another similar product in the same indication may be approved if the holder of the orphan designation is unable to supply sufficient quantities of the product or if the second applicant can establish clinical superiority of its product.

On April 26, 2023, the European Commission presented a draft for a comprehensive reform of the pharmaceutical legislation. The so-called "EU pharmaceutical package" 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.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to later-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

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

eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of IPF and LPE as well, which could give such products significant regulatory and market timing advantages over LTI-03 and LTI-01 or other product candidates that we may identify. Currently, off-label use of fibrinolytics is utilized in many hospitals for the treatment of LPE. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If competitors obtain patent protection or market exclusivity for their products before any of our products are approved, they could significantly delay the approval, and even review (in some cases), of our marketing application. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including, but not limited to:

- our inability to design or obtain such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

We have Cav1-related peptides in preclinical development for potentially a broad number of fibrosis indications. Many of these fibrosis indications may require a systemically delivered formulation to effectively treat these indications. We have not finalized a systemic formulation of a proprietary Cav1-related peptide and are currently developing potential systemic formulations. In the event we are unable to successfully complete a suitable formulation for therapeutic delivery, we may not be able to develop product candidates to address additional fibrosis indications. Even if we are able to develop a systemic formulation, it is possible that this systemic delivered product candidate will fail to show sufficient efficacy or safety in later stages of testing to proceed with development.

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, Novartis AG, and Pliant Therapeutics, Inc. 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 will reconsider 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.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. 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.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. Notwithstanding our current license and collaboration agreement with Taiho, we may not be able to enter into future collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all, which may result in being unable to successfully commercialize our products. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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, LTI-01 or any other product candidate we develop 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. Our belief that LTI-01 compares well on dosing schedule, surgical referrals and side effect profile compared to off-label IPFT treatment, such as tPA with DNase, to treat LPE patients is based upon limited data from our completed clinical trials. 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 and LTI-01 are in early stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for LTI-03, LTI-01 or any of our future product candidates 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 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.

Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies due to quality manufacturing concerns;
- the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics that may be required in connection with approval of our therapeutic product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain marketing approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

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

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.

The above-mentioned 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.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom, or the UK, as a result of the withdrawal of the UK from the EU, commonly referred to as Brexit. Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of product candidates in the UK.

The UK is no longer part of the European Single Market and EU Customs Union. Though a significant proportion of the regulatory framework for pharmaceutical products in the UK covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, there are some significant changes made to the regulatory framework to address the UK's departure from the EU.

The Medicines and Healthcare products Regulatory Agency, or the MHRA, is the national regulator responsible for supervising medicines and medical devices in the UK, comprising England, Scotland, Wales, and Northern Ireland. England, Scotland, and Wales form Great Britain which follows domestic law, whereas Northern Ireland currently continues to be subject to EU rules under the Northern Ireland Protocol. The main domestic legislation regulating medicines in the UK is the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR. The HMR has incorporated into domestic law some of the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU and has been amended to take into account the country's departure from the EU. Other domestic law implements the other corpus of EU medicines law that existed prior to the UK's departure from the EU.

Following Brexit, national marketing authorizations in the UK can be obtained to cover the whole of the UK (UKMA(UK)), Great Britain (UKMA(GB)) or Northern Ireland (UKMA(NI)), through the different available marketing authorization routes. Northern Ireland also continues to participate in the EU marketing authorization routes. In this case, the UK for the purpose of Northern Ireland can be a concerned member state (not a reference member state) for medicines going through the decentralized or mutual recognition procedure. Northern Ireland can also be included within the scope of the centralized procedure.

Any marketing authorizations granted by the MHRA under the decentralized or mutual recognition procedure before Brexit became national marketing authorizations covering the whole of the UK. Centrally authorized products were converted to a UKMA(GB) on January 1, 2021 unless the marketing authorization holder informed the MHRA otherwise, and centrally authorized products continued to be recognized in Northern Ireland. Until December 31, 2023, the European Commission Decision Reliance Procedure (ECDRP) could be used to obtain a UKMA(GB) with the MHRA relying on a decision taken by the European Commission on the approval of a new MA under the centralized procedure. Similarly, the MHRA can grant UKMA(UK) or UKMA(GB) marketing authorizations under the decentralized and mutual recognition reliance procedure (MRDCRP).

From January 1, 2024, the ECDRP will be replaced by a new International Recognition Procedure (IRP). The MRDCRP will be incorporated within the IRP. ECDRP and MRDCRP submissions received by the MHRA before January 1, 2024 will continue to follow existing procedures, but for ECDRP applications the CHMP positive opinion (but not necessarily the European Commission Decision) should be received before December 31, 2023. The IRP procedure is open to applicants who have received an authorization for the same product in one of the MHRA's

specified Reference Regulators. The current Reference Regulators include (among others) the FDA, EMA and the national competent authorities of the EU / EEA countries.

The start dates of the data and market exclusivity periods for medicines in the UK will depend on which route it was granted. In respect to orphan drugs, the general position under the HMR is 10 years' orphan market exclusivity is awarded from the date of authorization by the MHRA (which can be reduced to six years at the end of the fifth year if the licensing authority is satisfied that the orphan criteria is no longer met). An additional two years may be granted where pediatric data requirements are met. A UK-wide orphan marketing authorization can only be granted in the absence of an active EU designation.

On February 27, 2023, the UK and the EU agreed the Windsor Framework which addresses (among other things) the supply of medicines into Northern Ireland. It provides that medicines must be approved and licensed on a UK-wide basis by the MHRA with the same labelling and packaging across the whole of the UK. The EMA will have no role in the approval of new medicines for Northern Ireland. The arrangement takes effect from January 1, 2025.

Since a significant proportion of the regulatory framework for pharmaceutical products in the UK covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, with some amendments made to address the UK's departure from the EU, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of product candidates in the UK. However, there are new routes to obtaining marketing authorizations available such as the IRP.

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.

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. 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 Federal Food, Drug, and Cosmetic Act, or 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 good manufacturing practices, or cGMP, and good clinical practices, or 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.

The FDA and comparable foreign regulatory agencies may initiate consent decrees or withdraw 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- rescinding approval of the application, restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA or a comparable foreign regulatory agency to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market, and similar restrictions apply in foreign jurisdictions. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling, if certain conditions are met. The FDA and other agencies, including the Department of Justice, actively enforce the laws and regulations prohibiting the promotion of false or misleading information or unapproved uses and a company that is found to have improperly promoted the product may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approval, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed.

In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in LTI-03 and LTI-01 even if we obtain marketing approval for either product candidate.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement and coverage for these products and related treatments will be available from government authorities, private health insurers and other organizations, and if reimbursement and coverage is available, the level of reimbursement and coverage. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the U.S. and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, we cannot be sure as to the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new products that we develop and for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Recently enacted and future legislation may increase the difficulty and cost for us and our future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain for any products that are approved in the U.S. or foreign jurisdictions.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any product candidates for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on

average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we, or any future collaborators, may receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This legislation resulted in aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031 under the CARES Act. These Medicare sequester reductions were suspended through the end of June 2022, with the full 2% cut resuming thereafter. 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 our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

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, or the 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 November 10, 2020, the Supreme Court heard oral arguments to a case challenging the ACA. On February 10, 2021, the Biden Administration withdrew the federal government's support for overturning the ACA. On June 17, 2021, the Supreme Court rejected this challenge to the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care and consider actions that will protect and strengthen that access. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic. We cannot predict how federal agencies will respond to such Executive Orders.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, group purchasing organizations, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt,

maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, the Travel Act of 1961, or the Travel Act, which has been used as a tool in the health care context to target kickback schemes prohibited under state law involving private insurance that would not otherwise be prohibited under federal law and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security 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 distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products. There are also federal and state consumer deception laws, with which we must comply.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal

expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

The prices of prescription pharmaceuticals in the U.S. and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S. 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 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

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, or SIP, to import certain prescription drugs from Canada into the U.S. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager, or PBM, services fees. It was originally set to go into effect on January 1, 202, but with the passage of the Inflation Reduction Act has been delayed by Congress to January 1, 2032.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs the Department of Health and Human Services, or HHS, to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or 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 the Department of Health and Human Services (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 Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 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. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would have been fully at risk of government action if our products were the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also have further heightened the risk that we would not have been able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products had been on the market for nine years.

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. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. 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. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. 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.

In the E.U., similar political, economic, and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the U.S. and the E.U., reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the E.U., the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Governments outside of the U.S. tend to impose strict price controls, which may adversely affect our revenues from the sales of our products, if any.

In most foreign countries, including the European Economic Area, or EEA, and the UK, the proposed pricing for certain drugs (in particular, prescription-only drugs) is subject to pricing regulations. In the EU, although Directive 89/105/EEC regulates the framework conditions for the pricing of medicinal products and Regulation (EU) 2021/2282 on health technology assessment (HTA), to become fully applicable in January 2025, provides for a coordinated approach to assessing the benefit of new therapies, the decisions on pricing and cost reimbursement remain in the responsibility of the member states. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to 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. In some countries, particularly member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures. Moreover, 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 distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A 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. In view of the recurring shortages of medicines, individual member states (especially Germany) have decided to adjust price regulations for particularly rare pediatric medicinal products. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical 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 prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the U.S. and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions.

Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws, unfair competition laws and laws on advertising in the healthcare sector of EU Member States, and in respect of the UK (which is no longer a member of the EU), the UK Bribery Act 2010 and laws on advertising and promotion in the pharmaceutical, medical devices and healthcare sectors. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. The UK has also recently concluded a public consultation on introducing new statutory requirements for disclosing industry payments in the healthcare sector. Further, certain company associations have adopted so-called transparency codes, according to which payments to certain groups in the healthcare sector must be published or are published voluntarily. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States, as well in as the UK. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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. 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 the 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.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws and regulations of the FDA, CMS and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA, CMS and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations will also increase. These laws and regulations may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics and maintain a quality management system, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

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 also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. 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 U.S. Foreign Corrupt Practices Act, or 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 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.

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. and our ongoing Phase 1b trial of LTI-03 in IPF patients in the UK, E.U. and Australia, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, we may seek to conduct clinical trials in the EEA and may become subject to additional European data protection laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or 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 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.

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.

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 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, LTI-01 or any other product candidate. 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.

The manufacture of our clinical and, if approved, commercial drug supply of LTI-01 involves a highly complex manufacturing process that is subject to a number of risks.

The manufacturing process for the development of clinical, and if approved, commercial supply for LTI-01 involves a complex, multi-step process involving mammalian-based cell expression of the proenzyme and harvest, viral inactivation, purification and filtration of LTI-01 drug substance which is then lyophilized into drug product. Manufacturing any biological drug, such as LTI-01, is highly complex and is subject to a number of risks, and failure can occur at any stage in the production process. If our manufacturing partners fail to achieve and maintain high quality controls, processing and manufacturing standards, including avoidance of manufacturing errors, defects or product failures, we could experience recalls or withdrawals of our products, delays in delivery, cost overruns or other problems that would adversely affect our business. If our manufacturing partners are unable to manufacture our products on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experience unanticipated technological problems or delays in production, our business would be adversely affected.

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. For example, we are reliant on one manufacturer as the sole drug substance manufacturer of LTI-01. 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 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.

Our existing collaborations and future collaborations are and will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to selectively establish partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Our existing collaborations and any future collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our existing collaborations and any future collaborations we enter into do not result in the successful research, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization also apply to the activities of any therapeutic collaborators.

Additionally, if one of our existing or future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical

companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

We have entered into a collaboration agreement with Taiho for the development of LTI-01 and may in the future seek to enter into collaborations with third parties for the development and commercialization of other product candidates. If we fail to enter into such collaborations, or our collaborations are not successful, we may be unable to continue development of such product candidates, we would not receive any contemplated milestone payments or royalties, and we could fail to capitalize on the market potential of such product candidates.

In November 2020, Lung entered into a license and collaboration agreement with Taiho for the development and commercialization of our clinical product candidate, LTI-01. In the first quarter of 2021, Lung received an up-front license payment of $5.0 million for the exclusive license to develop and commercialize LTI-01 in Japan.

Pursuant to the Taiho Agreement, we are eligible to receive a milestone payment, transfer supply payments for manufacture of clinical and commercial supplies of LTI-01 and royalties on annual nets sales of LTI-01. If we are unable to successfully advance the development of our product candidates or achieve milestones, including pursuant to the Taiho Agreement, we will not receive any revenue and cash resources from milestone and royalty payments under our collaboration agreements.

In addition, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and a material and adverse effect on our business, financial condition, results of operations and prospects.

If we decide to seek to establish collaborations, but are not able to establish those collaborations, we may have to alter our development and commercialization plans.

Our development of our product candidates and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a

challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all, if and when we seek to enter into collaborations. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from sales of drugs.

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.

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.

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.

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. 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.

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 with patents 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 so 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 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.

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.

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

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.

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. We have a license to one U.S. patent 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, which is expected to expire in 2024 without patent term extension. We cannot assure that once the patent life has expired, we will not face competition from competitive products. Given the limited patent life, we will be relying 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 obtain approval of competing products following our patent expiration, 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. 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

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As our clinical development and commercialization plans and strategies develop, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including, but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for LTI-03, LTI-01 and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize LTI-03, LTI-01 or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

If we lose key management personnel or consultants, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel and consultants. We are highly dependent on our management, scientific and medical personnel and consultants. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors and consultants, and our inability to find suitable replacements could result in delays in product development and harm our business. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our key employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel and consultants.

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.

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

Any unplanned event, such as flood, fire, explosion, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. 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, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, including due to the impact of the COVID-19 pandemic, 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 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.

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.

In the past we have received written notification from the Nasdaq Stock Market, or Nasdaq, informing us that we were not in compliance with certain continued listing requirements of the Nasdaq Capital Market. As previously disclosed, on December 16, 2021, we received a deficiency letter from the Listing Qualifications Department of Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Bid Price Rule. On June 7, 2022, we received notification from Nasdaq notifying us that we were provided an additional 180 calendar day period or until December 5, 2022 to regain compliance with the Bid Price Rule.

We completed a 1-for-20 reverse stock split on our common stock on November 10, 2022. We regained compliance with the Bid Price Rule after the closing bid price of our common stock was above $1.00 per share for 10

consecutive business days from November 11, 2022 to November 25, 2022. On November 28, 2022, we received a letter from Nasdaq notifying us that we had regained compliance with the Bid Price Rule and we have remained in compliance.

In addition, on January 4, 2024, we received written notice, or the Notice, from the Listing Qualifications Department of Nasdaq stating that we failed to hold our annual meeting of shareholders within twelve months after our fiscal year ended December 31, 2022, as required by Nasdaq Listing Rule 5620(a), or the Annual Meeting Listing Rule. The Notice does not result in the immediate delisting of our common stock from the Nasdaq Capital Market.

The Notice stated that we have 45 calendar days, or until February 20, 2024, to submit a plan to regain compliance with the Annual Meeting Listing Rule. On January 31, 2024, we submitted a plan (which conveyed our intention to hold our 2023 annual meeting of stockholders on February 28, 2024) to regain compliance with the Annual Meeting Listing Rule within the required time frame. On February 20, 2024, we were notified that Nasdaq had accepted our plan and granted us an extension until February 28, 2024 to regain compliance. On February 28, 2024, we held our 2023 annual meeting of stockholders and on February 29, 2024, we received a letter from Nasdaq notifying us that we had regained compliance with the Annual Meeting Listing Rule and we have remained in compliance.

Furthermore, in connection with the Lung Acquisition, we issued 19,903 shares of Series X Convertible Preferred Stock, which are convertible into an aggregate of 19,903,000 shares of our common stock. Nasdaq Listing Rule 5110(a) provides that a company must apply for initial listing in connection with a transaction whereby a company combines with a non-Nasdaq entity, resulting in a change of control of such company and potentially allowing the non-Nasdaq entity to effectively obtain Nasdaq listing. In determining whether a change of control has occurred, Nasdaq considers all relevant factors including, changes in management, board of directors, voting power, ownership and financing structure of the company. If Nasdaq does not agree with our determination that the Lung Acquisition and the issuance of shares of our common stock and Series X Preferred Stock pursuant to the Lung Acquisition Agreement did not result in a change of control, we will be in violation of Nasdaq Listing Rule 5110(a) and our common stock could be delisted from 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 Nasdaq. 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 enrollment or results of our current Phase 1b clinical trial of LTI-03;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for LTI-03, LTI-01 or our other product candidates 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, LTI-01 or any other product candidate;
- changes in laws or regulations applicable to LTI-03, LTI-01 or any other product candidate, 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, LTI-01 or any other product candidate;
- 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. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline 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.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700.0 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we have incurred and we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs, and make some activities more time-consuming and costly.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 and the elimination of loss carrybacks for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The CARES Act delayed the 80% net operating loss limitation and allowed losses to be carried back five years for net operating losses generated in years beginning after December 31, 2017 and before December 1, 2021. 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.

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation has been 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.

Regulatory guidance under the 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 TCJA, the IRA, and additional tax legislation.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2023, we had federal net operating loss carryforwards of $56.5 million, of which $2.9 million will, if not utilized, begin to expire in 2036. As of December 31, 2023, we had state net operating carryforwards of $8.2 million, which will, if not utilized, begin to expire in 2043. Our federal research and development tax credit carryforwards of $1.1 million will, if not utilized, begin to expire in 2035. We also have federal orphan drug tax credit carryforwards of $6.7 million which begin to expire in 2039. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses or research and development tax credit carryforwards.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses or research and development tax credit carryforwards.

In addition, as described above in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the TCJA, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing net operating loss carryforwards that may significantly impact our ability to utilize our net operating losses to offset taxable income in the future.

Furthermore, under Section 382 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of the Company's acquisition of Lung Therapeutics, the tax attributes have been limited under Section 382. The Company has reflected the reduction of these tax attributes within the income tax footnote at December 31, 2023.

There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses, or other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities. In addition, state net operating losses generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our net operating losses and other tax attributes.

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

We currently 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 April 12, 2024, we had 16,972,512 shares of common stock outstanding and 12,523 shares of our Series X Preferred Stock outstanding, which were convertible into 12,523,000 shares of common stock, subject to beneficial ownership limitations.

Concurrently and in connection with the execution of the Lung Acquisition Agreement, our directors and officers as of immediately after the Lung Acquisition, and the directors and officers of the majority shareholder of Lung immediately prior to the Lung Acquisition, entered into lock-up agreements with us, pursuant to which each such director, officer or stockholder is subject to a 180-day lockup on the sale or transfer of shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock (including without limitation, shares of common stock or such other securities which may be deemed to be beneficially owned by each such director, officer or stockholder in accordance with the rules and regulations of the SEC and our securities which may be issued upon exercise of an option to purchase shares of common stock or a warrant to purchase shares of common stock) that were held by each such director, officer or stockholder at the closing of the Lung Acquisition and hereafter owned by each such director, officer or stockholder, including those shares issued in the Lung Acquisition, subject to certain customary exceptions. Upon expiration of this 180-day lockup period, these shares will become eligible for sale in the public market.

On the closing of the Financing, we entered into a Registration Rights Agreement with the Investors. Pursuant to the Registration Rights Agreement, we filed a resale registration statement with the SEC on January 29, 2024, which was declared effective on February 5, 2024. 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 Investor 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 April 12, 2024, entities and individuals affiliated with Bios Partners, or collectively, the Bios Entities, beneficially owned 9.99% 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 the Financing.

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 April 12, 2024, own 45.8% 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 assess material risks from cybersecurity threats on an ongoing basis, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. As our company grows, we plan to expand our strategy for cybersecurity in alignment with nationally accepted standards. We have not encountered cybersecurity risks that have materially affected or are reasonably likely to materially affect us or our business strategy. 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. While all of our personnel play a part in managing cybersecurity risks, 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 executive officers are responsible for the day-to-day management of the material risks that we face. Our Audit Committee, comprised of members with substantial experience in information technology governance and risk management, oversees our cybersecurity strategy. They are advised by a virtual CISO consultant with Certified Information Security Manager (CISM) and Certified Information Systems Security Professional (CISSP certifications, as well as extensive background in IT infrastructure, risk mitigation, and incident response planning. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving 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.

Item 2. Properties

Lung Therapeutics LLC, our wholly owned subsidiary, leased a facility containing 6,455 square feet of office space, which is located at 3801 S. Capital of Texas Hwy, Suite 330, Austin, Texas. The lease expired on March 31, 2024. We do not plan to renew the lease following its expiration and plan to operate virtually.

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 "ALRN" on the Nasdaq Capital Market and has 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 April 12, 2024, there were approximately 467 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.

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 two product candidates in clinical development, LTI-03 and LTI-01, and multiple candidates in preclinical development focused on fibrosis indications. Our pipeline includes:

- LTI-03, a peptide, for which we are currently recruiting patients for a Phase 1b dose-ranging, placebo-controlled safety, tolerability, and pharmacodynamic biomarker activity trial in development for the treatment of 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 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.

Prior to the termination of development of our main product candidate in February 2023 and the acquisition of Lung (as described below), our focus was the development of our main product candidate, ALRN-6924, a MDM2/MDMX dual inhibitor that leveraged our proprietary peptide drug technology. Since our inception, we have devoted a substantial portion of our resources to developing our product candidates, including ALRN-6924, developing our proprietary stabilized cell-permeating peptide platform, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations.

Announcement of Exploration of Strategic Alternatives

In February 2023, we announced a review of initial data from our Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer. Based on these findings, we decided to terminate the Phase 1b breast cancer trial and further development of ALRN-6924. We also announced that we were exploring a range of strategic alternatives to maximize shareholder value. We engaged Ladenburg Thalmann & Co., Inc. to act as a strategic advisor for this process. Strategic alternatives that were being evaluated included, but were not limited to, an acquisition, a merger, a business combination, a sale of assets or other transactions. In addition, in February 2023, we determined to reduce our workforce from nine to three full-time employees, which we completed in the second quarter of 2023.

The Lung Acquisition

On October 31, 2023, we acquired Lung Therapeutics, Inc., or Lung, pursuant to an Agreement and Plan of Merger, or the Lung Acquisition Agreement. Following our acquisition of Lung, or the Lung Acquisition, the business conducted by Lung became the business primarily conducted by the Company and we shifted our operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications.

Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, we issued to the stockholders of Lung 344,345 shares of our common stock and 19,903 shares of our newly designated Series X Preferred Stock. Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. In addition, we assumed (i) all Lung stock options and all warrants exercisable for Lung common stock immediately outstanding prior to the closing of the Lung Acquisition, each subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, we entered into a Stock and Warrant Purchase Agreement, or the Purchase Agreement, with a group of accredited investors, or the Investors, led by Bio Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, and including Nantahala Capital, as well as additional undisclosed investors, pursuant to which we issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants to purchase up to an aggregate of 2,353,500 shares of common stock, or the Warrant Shares, for an aggregate purchase price of approximately $18.4 million, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately $1.6 million issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X Preferred Stock,, or the Financing, and collectively with the Lung Acquisition, the Transactions. The Financing closed on November 2, 2023.

On February 28, 2024, we held our 2023 annual meeting of stockholders in which our stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of our outstanding Series X Preferred Stock. Following approval of the conversion of outstanding Series X Preferred Stock, the Company had approximately 29,495,512 shares of common stock issued and outstanding on a pro forma basis, which gives effect to the full conversion of the Series X Preferred Stock as of the date of our 2023 annual meeting of stockholders, without regard to beneficial ownership limitations that may limit the ability of certain holders of Series X Preferred Stock to convert such shares to common stock as such time. On March 5, 2024, based upon existing beneficial ownership limitations, 12,087 shares of Series X Preferred Stock were automatically converted into 12,087,075 shares of common stock. The remaining approximately 12,522 shares of Series X Preferred Stock (which are convertible into 12,522,925 shares of common stock) will remain convertible at the option of the holder thereof, subject to certain beneficial ownership limitations.

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, $131.2 million from sales of preferred stock prior to our IPO, $34.9 million from a collaboration agreement in 2010, and $18.4 million in gross proceeds, less issuance costs of $0.9 million, in connection with the Financing following the Lung Acquisition, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately $1.6 million issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X Preferred Stock.

Since our inception, we have incurred significant losses on an aggregate basis. Our net losses were $15.7 million and $27.3 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $288.5 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. In February 2023, we discontinued development of ALRN-6924 which substantially reduced our operating expenses. Notwithstanding these events, we expect to continue to incur operating losses for the foreseeable future.

After the Lung Acquisition, we believe that, based on our current operating plan, our cash and cash equivalents of $17.3 million as of December 31, 2023, will enable us to fund our operating expenses into the fourth quarter of 2024 following the date of this Annual Report on Form 10-K. We have concluded that as of the date of this Annual Report on Form 10-K there is substantial doubt about our ability to continue as a going concern. Our funding estimates are based on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect, see “Liquidity and Capital Resources.” We intend to fund our operations primarily through utilization of our current financial resources and additional raises of capital. Our future viability is dependent on our ability to raise additional capital, enter into a financing, consummate a successful acquisition, merger, business

combination, or a sale of assets or other transaction. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

Components of Aileron'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 its product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of manufacturing product candidates for use in its 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 its 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 used our employee and infrastructure resources across our development programs. We tracked outsourced development costs and milestone payments made under our licensing arrangements by product candidate or development program, but we did 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 candidate 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 have required 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 experienced significant trial delays due to patient enrollment or other reasons, we would have been 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 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.

Restructuring Costs

Restructuring-related charges are comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

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 gains or losses recognized from non-routine items such as accretion on short-term investments, and gains or losses recognized from foreign currency transactions, and the disposal of fixed assets.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following tables summarize our results of operations for the years ended December 31, 2023 and 2022 in thousands:

	Year Ended December 31,		Increase
	2023	2022	(Decrease)
Operating expenses:			
Research and development	$ 3,991	$ 17,967	(13,976)
General and administrative	11,357	9,680	1,677
Restructuring and other	928	—	928
Total operating expenses	16,276	27,647	(11,371)
Loss from operations	(16,276)	(27,647)	11,371
Other income, net	544	318	226
Net loss	$ (15,732)	$ (27,329)	$ 11,597

Research and Development Expenses

	Year Ended December 31,		Increase
	2023	2022	(Decrease)
Direct research and development services	$ 2,406	$ 12,145	$ (9,739)
Employee related expenses	1,214	3,266	(2,052)
Professional fees for services	324	2,166	(1,842)
Facilities and other expenses	47	390	(343)
Total research and development expenses	$ 3,991	$ 17,967	$ (13,976)

Research and development expenses for the year ended December 31, 2023 were $4.0 million, compared to $18.0 million for the year ended December 31, 2022. The decrease of $14.0 million was primarily a result of reduced spending of $6.0 million for our completed Phase 1b NSCLC trial, $1.6 million for our completed healthy volunteer study, $2.6 million for our terminated Phase 1b breast cancer trial, $2.0 million for ALRN-6924 manufacturing costs, and $1.0 million for other research expenses, and reduced spending of $2.7 million for employee related expenses and facilities and other expenses, offset by the research and development expense of $1.4 million and employee related expenses of $0.5 million incurred by Lung during 2023 after the acquisition.

General and Administrative Expenses

	Year Ended December 31,		Increase
	2023	2022	(Decrease)
Employee related expenses	$ 2,723	$ 3,068	$ (345)
Professional fees for services	7,053	4,633	2,420
Facilities and other expenses	1,581	1,979	(398)
Total general and administrative expenses	$ 11,357	$ 9,680	$ 1,677

General and administrative expenses were $11.4 million for the year ended December 31, 2023, compared to $9.7 million for the year ended December 31, 2022. The increase of $1.7 million in general and administrative expense was primarily the result of $2.4 million more professional fees during 2023 as compared to the year 2022 mainly due to the acquisition in October 2023, offset by $0.3 million lower headcount costs and $0.4 million lower facilities and other expenses during 2023 as compared to the year 2022.

Restructuring and Other

On February 16, 2023, our Board of Directors determined to reduce the Company's remaining workforce from nine to three full-time employees. The determination to affect the workforce reduction was made in connection with our decision to terminate the Phase 1b breast cancer trial of ALRN-6924 and further development of ALRN-6924.

As a result of the above restructuring initiatives, we incurred restructuring-related charges of $0.9 million for the year ended December 31, 2023. Restructuring-related charges were comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

Other Income, net

Other income, net of $0.5 million for the year ended December 31, 2023 consisted of interest income of $0.4 million and investment accretion of $0.2 million. 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, 2023, we had federal and state net operating loss carryforwards of $56.5 million and $8.2 million, respectively, which begin to expire in 2036 and 2043, respectively. As of December 31, 2023, we also had federal research and development tax credit carryforwards of $1.1 million, which begin to expire in 2035. The Company also has federal orphan drug tax credit carryforwards of $6.7 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 Company's acquisition of Lung Therapeutics, the tax attributes have been limited under Section 382. The Company has reflected the reduction of these tax attributes within the income tax footnote at December 31, 2023.

On October 31, 2023, the Company acquired, in accordance with the terms of the Merger Agreement, the stock of Lung Therapeutics. In accordance with ASC 805-740-25-3, 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 740-10-55-63 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.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses on an aggregate basis. We have not commercialized any product candidates, and as we do not have any product candidates under development, we do not expect to generate revenue from sales of any products. We have financed our operations through sales of common stock in our initial public offering and follow-on public offerings, sales of common stock and warrants in a private placement, sales of common stock in "at-the-market" offerings, sales of common stock under our equity line with Lincoln Park Capital LLC, or LPC, sales of preferred stock prior to our initial public offering, payments received under a collaboration agreement and sales of common stock, preferred stock and warrants in connection with the Lung Acquisition and the Financing. As of December 31, 2023, we had cash and cash equivalents of $17.3 million.

At-the-Market Program

In January 2021, we entered into a Capital on Demand Sales Agreement, or the ATM Sales Agreement, with JonesTrading Institutional Services LLC, or JonesTrading, and William Blair & Company, L.L.C., or William Blair, as agents, under which we may issue and sell shares of common stock, having an aggregate offering price of up to $30.0 million. Sales of common stock through JonesTrading and William Blair may be made by any method that is deemed an "at the market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. We are not obligated to make any sales of common stock under the ATM Sales Agreement. Pursuant to a prospectus relating to the ATM Sales Agreement we filed with the SEC on June 21, 2022, we may offer and sell shares of our common stock having an aggregate offering price of up to $14.0 million under the ATM Sales Agreement. There were no sales under the ATM Sales Agreement during the year ended December 31, 2023, or the year ended December 31, 2022.

Equity Line Financing

On September 21, 2020, we entered into a purchase agreement, or the Equity Line Purchase Agreement, with LPC for an equity line financing. The Equity Line Purchase Agreement provided that, subject to the terms and conditions set forth therein, we had the right, but not the obligation, to sell to LPC, and LPC is obligated to purchase up to $15.0 million of shares of common stock at our sole discretion, over a 36-month period that commenced in October 2020. We filed a registration statement on Form S-1 covering the sale of shares of common stock that are issued to LPC under the Equity Line Purchase Agreement, which was declared effective on October 15, 2020. The Equity Line Purchase Agreement was terminated in October 2023 pursuant to the terms thereof.

There were no sales under the Equity Line Purchase Agreement during the years ended December 31, 2023 and 2022.

The Lung Acquisition and Financing Transaction

On October 31, 2023, we acquired Lung, a privately held biopharmaceutical company focused on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications that have no approved or limited effective treatments. Immediately following the acquisition of Lung, we entered into a definitive agreement for the sale of (i) 4,707 shares of Series X Non-Voting Convertible Preferred Stock, at par value of $0.001, or the Series X Preferred Stock, and (ii) warrants to purchase an aggregate of 2,353,500 shares of Aileron's common stock in a private placement to a group of accredited investors led by Bios Partners, all affiliated entities are collectively called Bios, and including Nantahala Capital, as well as additional undisclosed investors, or the Financing.

The Financing resulted in gross proceeds to Aileron of approximately $18.4 million, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately $1.6 million issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X Preferred Stock. The Financing closed on November 2, 2023.

The exercise price of the Warrants is $4.89 per share, subject to certain price and share adjustments, including for stock splits, stock dividends, recapitalizations, subdivisions, combinations, noncash distributions and cash dividends. The Warrants issued under the Financing will be exercisable any time after May 2, 2024, and on or prior to May 2, 2027. Payment for Warrant shares upon exercise of the Warrants may be (i) in cash or (ii) in the event that there is no registration statement available for the resale of Warrant shares, by cashless exercise.

Under the terms of the Warrants, the Company shall not effect the exercise of any portion of any Warrant, and 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 common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may, upon written notice to the Company, increase or decrease such percentage to any other percentage not in excess of 19.99%; provided that any

increase or decrease in such percentage will not be effective until 61 days after such notice is delivered to the Company.

In connection with the Financing, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with certain investors. Pursuant to the Registration Rights Agreement, we filed a resale registration statement with the SEC on January 29, 2024, which was declared effective on February 5, 2024. The Registration Rights Agreement also contains customary terms, including an obligation to indemnify the investors, their officers, directors, agents, partners, members, managers, stockholders, affiliates and employees under the registration statement from certain liabilities and pay all fees and expenses (excluding any underwriting discounts and selling commissions and all legal fees and expenses of legal counsel for the investors, except for reasonable and documented fees and expenses in an amount not to exceed $30,000 of the investors that hold a majority in interest of the registrable securities in connection with the review of the registration statement) incident to our obligations under the Registration Rights Agreement.

Cash Flows

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

	Year Ended December 31,	
	2023	2022
Cash used in operating activities	$ (19,808)	$ (24,865)
Cash provided by investing activities	16,196	26,459
Cash provided by financing activities	15,794	—
Effect of exchange rate changes on cash and cash equivalents	(63)	—
Net increase in cash, cash equivalents and restricted cash	$ 12,119	$ 1,594

Operating Activities

During the year ended December 31, 2023, operating activities used $19.8 million of cash, primarily resulting from our net loss of $15.7 million and cash provided by the change in operating assets and liabilities of $5.4 million offset by non-cash charges of $1.3 million. Non-cash charges resulted primarily from stock-based compensation expense of $1.2 million. Changes in our operating assets and liabilities during the year ended December 31, 2023 consisted primarily of an increase of $5.0 million in accounts payable, and $0.4 million in accrued expenses and other current liabilities.

During the year ended December 31, 2022, operating activities used $24.9 million of cash, primarily resulting from our net loss of $27.3 million and cash provided by the change in operating assets and liabilities of $0.4 million offset by non-cash charges of $2.0 million. Non-cash charges resulted primarily from stock-based compensation expense. Changes in our operating assets and liabilities during the year ended December 31, 2022 consisted primarily of a decrease of $1.6 million in accrued expenses and other current liabilities, a decrease of $1.6 million in prepaid expense and other assets, and an increase of $0.5 million in accounts payable.

Investing Activities

During the year ended December 31, 2023, investing activities provided $16.2 million of cash. We received $16.3 million of proceeds from the maturities of investments, offset by $0.1 million of cash and cash equivalents from the Lung Acquisition.

During the year ended December 31, 2022, investing activities provided $26.5 million of cash. We received $48.3 million of proceeds from the sale of investments, offset by $21.9 million of purchases of investments.

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was $15.8 million due to the proceeds of $15.8 million from the Financing in October 2023.

During the year ended December 31, 2022, net cash provided by financing activities was $0 million.

Off-Balance Sheet Arrangements

As of December 31, 2023 and 2022 and in the periods presented, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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;
- 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
- 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.

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.

Contractual Obligations

Our wholly owned subsidiary, Lung Therapeutics LLC, leased a facility containing 6,455 square feet of office space located at 3801 S. Capital of Texas Hwy, Suite 330, Austin, Texas, which expired on March 31, 2024. We do not plan on renewing the lease. Following expiration of the lease, we plan to operate virtually.

Our remaining contractual rent commitment under this lease was less than $0.1 million as of December 31, 2023. For a description of our lease obligations, refer to Note 15 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Emerging Growth Company Status

We ceased to qualify as an emerging growth company as of December 31, 2022, and are now subject to Section 14A(a) and (b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, beginning with our fiscal year that started January 1, 2023. However, notwithstanding the loss of our status as an emerging growth company, we will continue to be exempt from Section 404(b) of the Sarbanes-Oxley Act of 2002 for so long as we are neither a "large accelerated filer" nor an "accelerated filer" as those terms are defined in Rule 12b-2 under the Exchange Act.

We are a "smaller reporting company" as defined in Rule 12b-2 under 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 Securities Exchange Act of 1934, as amended, 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

None.

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 Securities Exchange Act of 1934, as amended, or 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 principal 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 of 1934). Based on that evaluation, our Chief Executive Officer and our principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2023, 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, 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 the Company's internal control over financial reporting was not effective as of December 31, 2023 as a result of the material weakness discussed below.

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. The material weaknesses primarily related to the accounting for the business combination with Lung Therapeutics, Inc., specifically the (i) lack of sufficient accounting and supervisory personnel to maintain appropriate segregation of duties relating to user access of the financial accounting system and who have the appropriate level of technical accounting experience and training, (ii) lack of evidence over reviews of account reconciliations and supporting schedules, and (iii) 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. In the year ended December 31, 2023, management identified material weaknesses related to the accounting for our acquisition of Lung, including a lack of

sufficient precision in the performance of reviews supporting the purchase price allocation accounting, and a lack of timely oversight over third-party specialists and the reports they produced to support the accounting for the acquisition.

We are implementing procedures to remediate these material weaknesses, including the hiring of a full-time additional employee in our accounting department, integration into one accounting system, third party accounting specialists and a more streamlined process in order to prepare and review financial information, however, our control environment needs improvement, and as a result we may be exposed to errors. Our remediation plan also includes the hiring of additional accounting employees and/or consultants with the specific technical accounting experience necessary to assist with complex, non-routine transactions and to support the timely completion of financial close procedures, the implementation of robust processes, and to assist with the preparation of financial statements and our compliance with SEC reporting obligations. Additionally, we intend to develop and implement consistent accounting policies, internal control procedures and provide additional training to our accounting and financial reporting personnel. While we are working to remediate such weakness as quickly and efficiently as possible, we cannot at this time, provide an estimate of the timeframe we expect in connection with implementing our plan to remediate the material weaknesses.

Changes in Internal Control Over Financial Reporting

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 quarter ended December 31, 2023 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 three months ended December 31, 2023, none of the Company's directors or executive officers adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) 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 SEC, with respect to our 2024 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, 2023 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.aileronrx.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 2024 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, 2023 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 2024 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, 2023 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 2024 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, 2023 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 2024 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, 2023 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 F2-F35 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				X
3.4	Amended and Restated By-laws of the Registrant	8-K	7/5/2017	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				X
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*	2006 Stock Incentive Plan, as amended	S-1^	6/2/2017	10.1	
10.2*	Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan	S-1^	6/2/2017	10.2	

10.3*	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan	S-1^	6/2/2017	10.3	
10.4*	2016 Stock Incentive Plan	S-1^	6/2/2017	10.4	
10.5*	Form of Incentive Stock Option Agreement under 2016 Stock Incentive Plan	S-1^	6/2/2017	10.5	
10.6*	Form of Nonstatutory Stock Option Agreement under 2016 Stock Incentive Plan	S-1^	6/2/2017	10.6	
10.7*	2017 Stock Incentive Plan	S-1^	6/19/2017	10.8	
10.8*	Form of Incentive Stock Option Agreement under 2017 Stock Incentive Plan	S-1^	6/19/2017	10.9	
10.9*	Form of Nonstatutory Stock Option Agreement under 2017 Stock Incentive Plan	S-1^	6/19/2017	10.10	
10.10*	2017 Employee Stock Purchase Plan	S-1^	6/19/2017	10.11	
10.11*	Aileron Therapeutics, Inc. 2021 Stock Incentive Plan, as amended				X
10.12*	Form of Stock Option Agreement under 2021 Stock Incentive Plan	10-K	3/20/2023	10.12	
10.13*	Form of Restricted Stock Unit Agreement under 2021 Stock Incentive Plan	10-K	3/20/2023	10.13	
10.14	Form of Director and Officer Indemnification Agreement	S-1^	6/19/2017	10.12	
10.15	License Agreement, dated as of December 31, 2006, by and between the Registrant and Materia, Inc. (now Umicore Precious Metals Chemistry USA, LLC)	S-1^	6/2/2017	10.13	
10.16++	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.	S-1^	6/19/2017	10.14	
10.17*	Amended and Restated Employment Agreement, dated as of September 6, 2018, between the Registrant and Manuel C. Alves Aivado, M.D., Ph.D.	10-Q	11/7/2018	10.2	
10.18*	Severance Agreement, dated as of September 6, 2018, between the Registrant and Manuel C. Alves Aivado, M.D., Ph.D.	10-Q	11/7/2018	10.3	
10.19*	Offer Letter, dated as of November 15, 2007, between the Registrant and D. Allen Annis, Ph.D.	10-K	3/29/2019	10.21	
10.20*	Severance Agreement, dated as of November 5, 2018, between the Registrant and D. Allen Annis, Ph.D.	10-K	3/29/2019	10.22	
10.21	Securities Purchase Agreement, dated March 28, 2019, by and among the Registrant and the persons party thereto	8-K	4/1/2019	10.1	
10.22	Registration Rights Agreement, dated March 28, 2019, by and among the Registrant and the persons party thereto	8-K	4/1/2019	10.4	

10.23	Form of Warrant to Purchase Common Stock	8-K	4/1/2019	10.3
10.24	Purchase Agreement, dated as of September 21, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	9/22/2020	10.1
10.25	Registration Rights Agreement, dated as of September 21, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	9/22/2020	10.2
10.26	Capital on Demand™ Sales Agreement, dated January 29, 2021, by and among Aileron Therapeutics, Inc. and JonesTrading Institutional Services LLC and William Blair & Company, L.L.C.	8-K	1/29/2021	1.1
10.27	Sublease Agreement, dated March 26, 2021, by and among the Company, Vittoria Industries North America, Inc. and Waterfront Equity Partners, LLC	10-Q	5/11/2021	10.1
10.28*	Separation and Release of Claims Agreement, dated July 8, 2022, by and between the Company and Vojislav Vukovic, M.D., Ph.D.	10-Q	8/15/2022	10.1
10.29*	Separation and Release of Claims Agreement, dated as of April 24, 2023, between the Registrant and D. Allen Annis, Ph.D.	10-Q	5/8/2023	10.1
10.30*	Consulting Agreement, dated as of April 15, 2023, between the Registrant and D. Allen Annis, Ph.D.	10-Q	5/8/2023	10.2
10.31	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
10.32#	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
10.33	Form of Registration Rights Agreement, by and among Aileron Therapeutics, Inc. and certain purchasers named therein	8-K	10/31/2023	10.2
10.34*	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
10.35*	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
10.36*	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
10.37+#	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

10.38+	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	
10.39+	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	
10.40+	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	
10.41+	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	
10.42*	Lung Therapeutics, Inc.2013 Long-Term Incentive Plan, as amended				X
16.1	Letter from PricewaterhouseCoopers LLP regarding change in certifying accountant	8-K	10/31/2023	16.1	
21.1	Subsidiaries of Aileron Therapeutics, Inc.				X
23.1	Consent of PricewaterhouseCoopers LLP, 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	Aileron Therapeutics, Inc. Compensation Recovery Policy	X
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**.**

Aileron Therapeutics, Inc.

Date: April 15, 2024

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

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Brian Windsor, Ph.D. and Charles T. Garner, each or any of them, such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing necessary or desirable to be done in and about the premises, as fully to all intents and purposes as such person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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)	April 15, 2024
/s/ Charles T. Garner **Charles T. Garner**	Senior Vice President, Finance (principal financial officer and principal accounting officer)	April 15, 2024
/s/ Josef H. Von Rickenbach **Josef H. Von Rickenbach**	Chairman of the Board of Directors	April 15, 2024
/s/ Manuel C. Aivado **Manuel C. Aivado, M.D. Ph. D.**	Director	April 15, 2024
/s/ Reinhard J. Ambros, Ph.D. **Reinhard J. Ambros, Ph.D.**	Director	April 15, 2024
/s/ William C. Fairey **William C. Fairey**	Director	April 15, 2024
/s/ Alan Musso **Alan Musso**	Director	April 15, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Aileron Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the balance sheet of Aileron Therapeutics, Inc. (the "Company") as of December 31, 2022, and the related statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the year then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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

The financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses and negative cash flows from operations and had an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 of these financial statements 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.

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/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 20, 2023

We served as the Company's auditor from 2009 to 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Aileron Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aileron Therapeutics, Inc. (the "Company") as of December 31, 2023, 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, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023 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.

Business Combination

Critical Audit Matter Description

As described in Note 3 to the financial statements, the Company acquired Lung Therapeutics, Inc. on October 31, 2023. This acquisition was accounted for as a business combination. We identified the evaluation of the acquisition-date fair value of the intangible assets acquired as a critical audit matter.

The principal consideration for our determination that the evaluation of the acquisition-date fair values of the intangible assets acquired was a critical audit matter is the high degree of subjective auditor judgment associated with evaluating management's determination of the fair values of the acquired intangible assets, which is primarily due to the complexity of the valuation models used and the sensitivity of the underlying significant assumptions. The key assumptions used within the valuation models included prospective financial information such as future revenue growth and an applied discount rate. The calculated fair values are sensitive to changes in these key assumptions.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to the evaluation of acquisition-date fair values of intangible assets acquired included the following, among others:

- We evaluated the reasonableness of the purchase price allocation 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 intangible assets.

- We tested the assumptions used within the discounted cash flow models to estimate the fair values of the intangible assets, which included key assumptions such as the future revenue growth and the applied discount rate.
- We assessed the reasonableness of management's forecast by inquiring with management to understand how the forecast was developed and comparing the projections to external sources, including industry trends and peer companies' historical data.
- We involved our internal valuation specialist who assisted in the evaluation and testing performed on the reasonableness of significant assumptions to the models, including the applied discount rate.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2024.

New York, NY
April 15, 2024

AILERON THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 17,313	$ 5,194
Investments	—	16,048
Prepaid expenses and other current assets	882	606
Restricted cash	25	25
Operating lease, right-of-use asset, current portion	46	—
Total current assets	18,266	21,873
Operating lease, right-of-use asset	—	40
Property and equipment, net	19	70
Goodwill	6,330	—
Intangible assets	79,200	—
Other non-current assets	2,193	24
Total assets	$ 106,008	$ 22,007
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,190	$ 1,720
Accrued expenses and other current liabilities	3,147	1,631
Operating lease liabilities, current portion	48	33
Total current liabilities	4,385	3,384
Deferred tax liability	3,326	—
Total liabilities	7,711	3,384
Commitments and contingencies (Note 15)		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2023 and at December 31, 2022; 24,610 shares issued and outstanding at December 31, 2023 and no shares issued and outstanding at December 31, 2022	91,410	—
Stockholders' equity:		
Common stock, $0.001 par value; 45,000,000 shares authorized at December 31, 2023 and December 31, 2022; 4,885,512 shares and 4,541,167 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	91	91
Additional paid-in capital	295,376	291,365
Accumulated other comprehensive loss	(63)	(48)
Accumulated deficit	(288,517)	(272,785)
Total stockholders' equity	6,887	18,623
Total liabilities, convertible preferred stock and stockholders' equity	$ 106,008	$ 22,007

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

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

(In thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Revenue	$ —	$ —
Operating expenses:		
Research and development	3,991	17,967
General and administrative	11,357	9,680
Restructuring and other costs	928	—
Total operating expenses	16,276	27,647
Loss from operations	(16,276)	(27,647)
Other income (expense), net	544	318
Net loss	$ (15,732)	$ (27,329)
Net loss per share—basic and diluted	$ (3.42)	$ (6.02)
Weighted average common shares outstanding—basic and diluted	4,598,715	4,539,318
Comprehensive loss:		
Net loss	$ (15,732)	$ (27,329)
Other comprehensive gain (loss):		
Unrealized gain on short-term investments, net of tax of $0	48	(35)
Foreign currency translation adjustments	(63)	—
Total other comprehensive loss	(15)	(35)
Total comprehensive loss	$ (15,747)	$ (27,364)

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

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

(In thousands, except share data)

	Convertible Series X Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Convertible Preferred Stock and Stockholders' Equity
Balances at December 31, 2021	—	$ —	4,528,667	$ 91	$ 289,282	$ (13)	$ (245,456)	$ 43,904
RSUs vested, net of shares repurchased for tax	—	—	12,500	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,083	—	—	2,083
Unrealized loss on investments	—	—	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	—	—	(27,329)	(27,329)
Balances at December 31, 2022	—	$ —	4,541,167	$ 91	$ 291,365	$ (48)	$ (272,785)	$ 18,623
Issuance of common stock in connection with business acquisition	—	—	344,345	—	403	—	—	403
Issuance of Series X preferred stock in connection with business acquisition	19,903	74,615	—	—	—	—	—	74,615
Stock options assumed in connection with business acquisition	—	—	—	—	1,050	—	—	1,050
Common stock warrants assumed in connection with business acquisition	—	—	—	—	627	—	—	627
Issuance of Series X preferred stock in connection with the Financing, net of issuance costs of $855	4,707	16,795	—	—	—	—	—	16,795
Issuance of common stock warrants in connection with the Financing, net of issuance costs of $38	—	—	—	—	741	—	—	741
Stock-based compensation expense	—	—	—	—	1,190	—	—	1,190
Unrealized gain on short-term investments	—	—	—	—	—	48	—	48
Foreign currency translation adjustments	—	—	—	—	—	(63)	—	(63)
Net loss	—	—	—	—	—	—	(15,732)	(15,732)
Balances at December 31, 2023	24,610	$ 91,410	4,885,512	$ 91	$ 295,376	$ (63)	$ (288,517)	$ 98,297

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

AILERON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (15,732)	$ (27,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	119	169
Net amortization of premiums and discounts on investments	32	(208)
Stock-based compensation expense	1,190	2,083
Gain on sale of property and equipment	(42)	—
Loss on disposition of property and equipment	6	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	51	1,613
Other assets	(3)	—
Accounts payable	(4,982)	510
Operating lease liabilities	(65)	(129)
Accrued expenses and other current liabilities	(382)	(1,574)
Net cash used in operating activities	(19,808)	(24,865)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	42	—
Purchases of investments	—	(21,850)
Proceeds from sales or maturities of investments	16,250	48,309
Acquisition, net of cash acquired	(96)	0
Net cash provided by investing activities	16,196	26,459
Cash flows from financing activities:		
Proceeds from the Financing	15,794	—
Net cash provided by financing activities	15,794	—
Effect of exchange rate changes on cash and cash equivalents	(63)	—
Net increase in cash, cash equivalents and restricted cash	12,119	1,594
Cash, cash equivalents and restricted cash at beginning of year	5,219	3,625
Cash, cash equivalents and restricted cash at end of year	$ 17,338	$ 5,219
Cash and cash equivalents at end of year	$ 17,313	$ 5,194
Restricted cash at end of year	25	25
Cash, cash equivalents and restricted cash at end of year	$ 17,338	$ 5,219
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized gain on short-term investments	$ 48	$ —
Fair value of common shares issued in the Lung Acquisition	$ 403	$ —
Fair value of Series X Preferred Stock issued in the Lung Acquisition	$ 74,615	$ —
Fair value of options assumed in the Lung Acquisition	$ 1,050	$ —
Fair value of warrants assumed in the Lung Acquisition	$ 627	$ —

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

AILERON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

1. Nature of the Business

Aileron Therapeutics, Inc. ("Aileron" or 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. Refer to Note 10 for more details on the restructuring event in 2023.

On October 31, 2023, Aileron acquired Lung Therapeutics, Inc. ("Lung Therapeutics" or "Lung") pursuant to an Agreement and Plan of Merger, dated October 31, 2023 (the "Lung Acquisition Agreement"), by and among the Company, AT Merger Sub I, Inc., a Delaware corporation and its wholly owned subsidiary, or First Merger Sub, AT Merger Sub II, LLC, a Delaware limited liability company and its wholly owned subsidiary, or Second Merger Sub, and Lung. Pursuant to the Lung Acquisition Agreement, First Merger Sub merged with and into Lung, pursuant to which Lung was the surviving entity and became its wholly owned subsidiary, or the First Merger. Immediately following the First Merger, Lung merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity, such merger, together with the First Merger, the Lung Acquisition. Lung was incorporated on November 13, 2012 under the laws of the state of Texas. 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, the Company 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 ("IPF") and has completed a healthy volunteer Phase 1a clinical trial. LTI-03 is currently in a Phase 1b clinical trial in IPF patients. The Company's second product candidate, LTI-01, is in development for loculated pleural effusion ("LPE"). The Company has completed Phase 1b and Phase 2a clinical trials in LPE patients.

Liquidity and Going Concern

In accordance with Accounting Standards Update ("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 were 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, 2023, the Company has financed its operations primarily through $145,467 in net proceeds from sales of common stock and warrants, $131,211 from sales of

preferred stock prior to its initial public offering ("IPO"), and $34,910 from a collaboration agreement in 2010, and $18,429 in gross proceeds, less issuance costs of $893, in connection with the financing following the Lung Acquisition, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately $1,553 issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X non-voting convertible preferred stock ("Series X Preferred Stock"), or the Financing, and collectively with the Lung Acquisition, the Transactions.

After the Lung Acquisition, management believes that, based on the Company's current operating plan, the Company's cash and cash equivalents of $17,313 as of December 31, 2023, will enable Aileron to fund its operating expenses and capital expenditure requirements for at least six months following the date of this Annual Report on Form 10-K. Since its inception, the Company has not generated any revenue from product sales and have never generated an operating profit. The Company has incurred significant losses on an aggregate basis. The Company's net losses were $15,732 and $27,329 for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company had an accumulated deficit of $288,517. 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. In February 2023, the Company discontinued development of ALRN-6924 which substantially reduced its operating expenses. Notwithstanding these events, management expects to continue to incur operating losses for the foreseeable future until the Company completes development and approval of its product candidates. The Company will continue to fund its operations primarily through utilization of its current financial resources and additional raises of capital.

These conditions raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date those consolidated financial statements are issued. The Company plans to address these conditions by raising funds from its current investors, potential outside investors and other funding 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. 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 a 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.

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 ("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 ("ASC") and as amended by ASUs of the Financial Accounting Standards Board ("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. 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 value of stock-based

compensation, the purchase price allocation for the Lung Acquisition, and the valuation of warrants. 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.

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 are measured at fair value on a recurring basis.

Restricted Cash

As of December 31, 2023 and December 31, 2022, restricted cash of $25 consisted of cash deposited in a separate restricted bank account as a security deposit for the Company's corporate credit cards.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. ASC 820, Fair Value Measurement ("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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

Computer equipment and software	3 to 5 years
Furniture and fixtures	7 years

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for leases under ASC Topic 842, Leases ("ASC 842"). Under ASC 842, at inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or financing leases. Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the Company's consolidated balance sheets.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. If a lease does not provide information to determine an implicit interest rate, the Company uses its incremental borrowing rate in determining the present value of lease payments. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease payments are expensed using the straight-line method as a general and administrative expense over the lease term. The depreciable life of assets and leasehold improvements are limited by the expected lease term unless there is a transfer of title or purchase option reasonably certain of exercise. The Company has elected to apply the practical short-term expedient to leases with a lease term of 12 months or less, which does not subject the leases to capitalization.

The Company has an operating lease of office space, which has a remaining lease term of less than one year and includes one or more options to renew or terminate early. The Company determines if an arrangement contains a lease at inception. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments, initial direct costs paid or incentives received. The Company's leases do not contain an implicit rate, and therefore the Company uses an estimated incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. Options to extend or terminate the lease are reflected in the calculation when it is reasonably certain that the option will be exercised. The Company has elected to account for lease and non-lease components as a single lease component, however non-lease components that are variable, such as common area maintenance and utilities, are generally paid separately from rent based on actual costs incurred and therefore are not

included in the right-of-use asset and operating lease liability and are reflected as an expense in the period incurred. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet.

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 ("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 Accounting Standards Update, or ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The Company’s goodwill and intangible assets are 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.

To date, the Company has not recorded any impairment losses on long-lived assets. For additional details regarding goodwill and intangible assets, refer to Note 7.

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, 2023. 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 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 based on the historical volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The 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 (the "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 (the "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 ("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 Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. 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.

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 diluted 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, outstanding options and warrants to purchase common stock are considered potential dilutive common shares.

Acquisition Accounting

The fair value of the consideration exchanged in a business combination is allocated to tangible assets and identifiable intangible assets acquired and liabilities assumed at acquisition date fair value. Goodwill is measured as the excess of the consideration transferred over the net fair value of identifiable assets acquired and liabilities assumed. The accounting for an acquisition involves a considerable amount of judgment and estimation. Cost, income, market or a combination of approaches may be used to establish the fair value of consideration exchanged, assets acquired, and liabilities assumed, depending on the nature of those items. The valuation approach is determined in accordance with generally accepted valuation methods. Key areas of estimation and judgment may include the selection of valuation approaches, cost of capital, market characteristics, cost structure, impacts of synergies, and estimates of terminal value, among other factors.

While the Company uses estimates and assumptions as part of the purchase price allocation process to estimate the fair value of assets acquired and liabilities assumed, estimates are inherently uncertain and subject to refinement. During the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the assets acquired and liabilities assumed, with a corresponding offset to goodwill, to the extent that adjustments are identified to the preliminary purchase price allocation. Upon conclusion of the measurement period, or final determination of the value of the assets acquired and liabilities assumed, whichever comes first, any subsequent adjustments are recorded to results of operations.

Recently Adopted Accounting Pronouncements

On January 1, 2023, the Company adopted ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, for the fiscal year beginning January 1, 2023 using the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as of the adoption date. Additionally, no prior period amounts were adjusted. The new standard adjusts the accounting for assets held on an amortized cost basis, including short-term investments accounted for as available-for-sale, and receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized

cost basis of the financial assets to present the net amount expected to be collected. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06—Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative, to clarify or improve disclosure and presentation requirements of a variety of Topics. ASU 2023-06 adds 14 of the 27 identified disclosure or presentation requirements to the Codification. However, each amendment in the ASU will only become effective if the SEC removes the related disclosure or presentation requirement from its existing regulations by June 30, 2027. The effective dates of ASU 2023-06 will depend, in part, on whether an entity is already subject to the SEC's current disclosure requirements. For such entities and those that must "file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer," the effective date for each amendment will be the date on which the SEC's removal of that related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years after the date of such removal. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07—Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, to improve the disclosures about a public entity's reportable segments and address requests from investors for additional, more detailed information about a reportable segment's expenses. All public entities will be required to report segment information in accordance with the new guidance starting in annual periods beginning after December 15, 2023. The Company plans to adopt the ASU for the fiscal year beginning January 1, 2024. Since the Company has only one reportable segment, the Company will need to disclose the title and position of the chief operating decision maker ("CODM") and an explanation of how the CODM uses the reported measures of segment profit or loss in assessing segment performance and deciding how to allocate resources, as well as disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the CODM. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09—Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information as well as certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this update are effective for annual periods beginning after December 15, 2024. The Company does not expect adoption of this ASU to have a material impact on its results of operations, financial condition, and its consolidated financial statements other than adding new disclosures, which the Company is currently evaluating, as the Company has not recorded any net tax provision for the periods presented due to the losses incurred and the need for a full valuation allowance on net deferred tax assets.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements and related disclosures upon adoption.

3. Business Acquisition

On October 31, 2023, Aileron acquired 100% of Lung, pursuant to the Lung Acquisition Agreement. At the closing of the Lung Acquisition, Aileron issued to the stockholders of Lung 344,345 shares of its common stock (excluding 221 fractional shares from the total 344,566 shares pursuant to the Lung Acquisition Agreement) and 19,903 shares of its newly designated Series X Preferred Stock (excluding 238 fractional shares from the total 20,141 shares pursuant to the Lung Acquisition Agreement). Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. The Company paid $290 cash in lieu of fractional shares of both common stock and Series X Preferred Stock. In addition, Aileron assumed all Lung's stock options (1,780,459) and all warrants (726,437)

exercisable for Lung common stock immediately outstanding prior to the closing of the Lung Acquisition, each subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into a Stock and Warrant Purchase Agreement (the “Purchase Agreement” or the "PIPE") with a group of accredited investors, pursuant to which Aileron issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants (the “Warrants”) to purchase up to an aggregate of 2,353,500 shares of Aileron common stock (the “Warrant Shares”), for an aggregate purchase price of approximately $18,429, which included the conversion of certain convertible promissory notes in the aggregate principal amount of $1,553 issued by Lung to Bios Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, at a 10% discount to the per share price of the Series X Preferred Stock. The Financing closed on November 2, 2023. Subject to stockholder approval for the conversion rights of the Series X Preferred Stock, each share of Series X Preferred Stock is convertible into 1,000 shares of common stock.

The net proceeds from the Financing of approximately $17,536 are expected to be used to advance Aileron’s clinical development pipeline, business development activities, working capital and other general corporate purposes.

The Lung Acquisition was accounted for under the acquisition method of accounting under ASC 805. Under the acquisition method, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on the fair values as of the date of the acquisition. Consideration transferred is the sum of the acquisition-date fair values of the assets transferred, the liabilities incurred by the acquirer to the former owners of the acquiree, and the equity interests issued by the acquirer to the former owners of the acquiree (except for the measurement of share-based payment awards). The total purchase price consideration consisted of the following:

Fair value of common stock issued to Lung stockholders	$	403
Fair value of Series X Preferred Stock issued to Lung stockholders		74,615
Cash in lieu of fractional shares		290
Fair value of the options assumed		1,050
Fair value of the warrants assumed		627
Total purchase price consideration	$	76,985

The Company recorded the assets acquired and liabilities assumed as of the date of the Lung Acquisition based on the information available at that date. The following table presents the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the Lung Acquisition date:

Assets acquired:		
Cash and cash equivalents	$	194
Prepaid expenses and other current assets		2,465
Property and equipment, net		3
Operating right-of-use assets		76
Goodwill		6,330
Indefinite-lived intangible assets		79,200
Other assets		27
		88,295
Liabilities assumed:		
Accounts Payable		4,452
Accrued expenses and other current liabilities		1,899
Operating lease liabilities, current		80
Convertible notes payable		1,553
Deferred tax liability		3,326
		11,310
Net assets acquired	$	76,985

Pro Forma Financial Information

The following pro forma financial information reflects the consolidated results of operations of the Company for the years ended December 31, 2023 and 2022, as if the Lung Acquisition had taken place on January 1, 2022. The unaudited pro forma financial information is not necessarily indicative of the results of operations as they would have been had the transactions been effected on the assumed date.

	Year Ended December 31,	
	2023	2022
Total net revenue	$ 153	$ 688
Net loss	(28,232)	(51,610)

The unaudited pro forma financial information above gives effect primarily to the following:

- The exclusion of Lung Acquisition related transaction costs from the year ended December 31, 2023, and the addition of these items to the year ended December 31, 2022.

4. 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, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 10,322	$ —	$ —	$ 10,322
	$ 10,322	$ —	$ —	$ 10,322

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 1,661	$ —	$ —	$ 1,661
Investments:				
Commercial paper	—	12,814	—	12,814
Treasury bills	—	3,234	—	3,234
	$ 1,661	$ 16,048	$ —	$ 17,709

During the years ended December 31, 2023 and 2022, there were no transfers between levels.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2023	2022
Prepaid research and development	$ 207	$ —
Other current assets	675	606
Total prepaid expenses and other current assets	$ 882	$ 606

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Computer equipment and software	$ 323	$ 340
Furniture and fixtures	54	—
	377	340
Less: Accumulated depreciation and amortization	(358)	(270)
	$ 19	$ 70

Depreciation expense for the years ended December 31, 2023 and 2022 was $49 and $169, respectively. During the year ended December 31, 2023, the Company received payment for disposed, fully depreciated assets, resulting in a gain on sales of $42.

7. Goodwill and Indefinite-Lived Intangible Assets

$6,330 of goodwill and $79,200 of indefinite-lived intangible assets acquired in the Lung Acquisition were recorded at fair value on the Lung Acquisition date (refer to Note 3 for more information). The Company performed a qualitative assessment of goodwill and indefinite-lived intangible assets for potential impairment as of December 31, 2023, and concluded that there was no goodwill or intangible assets impairment as of December 31, 2023.

8. Other Assets

Other assets consisted of the following:

	December 31,	
	2023	2022
Non-current prepaid research and development	$ 2,140	$ —
Other assets	53	24
Total other non-current assets	$ 2,193	$ 24

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
External research and development services	$ 1,110	$ 533
Payroll and payroll-related costs	1,178	425
Professional fees	653	492
Other	206	181
Total accrued expenses and other current liabilities	$ 3,147	$ 1,631

10. Restructuring and Other Costs

On February 16, 2023, the Board of Directors of the Company determined to reduce the Company's remaining workforce from nine to three full-time employees. The determination to effect the workforce reduction was made in connection with the Company's decision to terminate its Phase 1b breast cancer trial of ALRN-6924 and further development of ALRN-6924.

As a result of the above restructuring initiatives, the Company incurred restructuring-related charges of $928 for the year ended December 31, 2023. Restructuring-related charges were comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

The Company paid all restructuring-related charges during the year ended December 31, 2023.

11. Preferred Stock

As of December 31, 2023, the Company had 5,000,000 shares of preferred stock, par value $0.001 per share, authorized, out of which 24,610 shares of Series X Preferred Stock were issued and outstanding. As of December 31, 2022, the Company had 5,000,000 shares of preferred stock, par value $0.001 per share, authorized, and no shares of preferred stock issued or outstanding.

On October 31, 2023 Aileron acquired Lung. Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, Aileron issued to the stockholders of Lung 344,345 shares of the common stock of Aileron, par value $0.001 per share, and 19,903 shares of Series X Preferred Stock.

Immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into the Purchase Agreement with a group of accredited investors, pursuant to which Aileron issued and sold 4,707 shares of Series X Preferred Stock and Warrants to purchase up to an aggregate of 2,353,500 shares of Aileron common stock. Refer to Note 3 for more details on the Financing in connection with the Purchase Agreement.

Since the Series X Preferred Stock was sold as a unit with the Warrants according to the Purchase Agreement, the proceeds received were allocated to each instrument on a relative fair value basis. Total gross proceeds of $18,429 reduced by $893 of the issuance costs were allocated as follows: $16,795 to the Series X Preferred Stock and $741 to the Warrants. The Series X Preferred Stock and the Warrants issued in the Financing were recorded at par value of $0.001.

The Company evaluated the Series X Preferred Stock for liability classification in accordance with the provisions of ASC 480, Distinguishing Liabilities from Equity ("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 (see below).

Subject to stockholders' approval, 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.

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. Additionally, the approval of the holders of a

majority of the Series X Preferred Stock is required for certain change of control transactions, provided that this approval right will terminate upon stockholders' approval of the conversion proposal.

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

Subject to stockholders' approval of the conversion proposal, 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.

At the 2023 Annual Meeting on February 28, 2024, the Company's stockholders approved the issuance of shares of common stock, upon conversion of its outstanding Series X Preferred Stock. Refer to Note 18 for more details on the 2023 Annual Meeting.

Redemption

Shares of the Series X Preferred Stock are not redeemable at the election of the holder except for in the event the Company would have been unable to obtain an affirmative stockholder vote at the 2023 Annual Meeting to permit conversion, each holder of Series X Preferred Stock would have been entitled to elect, at the holder's option, to have the shares of Series X Preferred Stock be redeemed by the Company and equal to the estimated fair value of the Series X Preferred Stock share at the time of redemption. Due to this redemption feature, as of December 31, 2023, the Series X Preferred Stock was classified within temporary equity on the consolidated balance sheet.

Maturity

The Series X Preferred Stock shall be perpetual unless converted.

12. Common Stock

As of December 31, 2023 and 2022, the Company was authorized to issue 45,000,000 shares of common stock, par value $0.001 per share. As of December 31, 2023, the Company had 4,885,512 shares of common stock issued and outstanding. As of December 31, 2022, the Company had 4,541,167 shares of common stock issued and outstanding.

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 of directors, if any. As of December 31, 2023 and 2022, 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

As disclosed above, on October 31, 2023, the Company issued to the stockholders of Lung 344,345 shares of the common stock of Aileron, par value $0.001 per share, under the terms of the Lung Acquisition Agreement. In addition, Aileron assumed (i) all Lung stock options immediately outstanding prior to the First Merger, each becoming an option for common stock subject to adjustment pursuant to the terms of the Lung Acquisition Agreement, and (ii) all warrants exercisable for Lung common stock immediately outstanding prior to the First Merger, each becoming a warrant to purchase common stock, subject to adjustment pursuant to the terms of the Lung Acquisition Agreement. Immediately following the closing of the Lung Acquisition, the Company had 4,885,512 shares of common stock issued and outstanding.

As disclosed in the Note 3 above, immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into the Purchase Agreement with a group of accredited investors, pursuant to which Aileron issued and sold 4,707 shares of Series X Preferred Stock and warrants to purchase up to an aggregate of 2,353,500 shares of Aileron common stock. The exercise price of the Warrants is $4.89 per share, subject to certain price and share adjustments, including for stock splits, stock dividends, recapitalizations, subdivisions, combinations, reclassifications, noncash distributions, and cash dividends. The Warrants will be exercisable any time after the later of May 2, 2024, the date the requisite stockholder approval is obtained, and on or prior to May 2, 2027. Payment for Warrant shares upon exercise of the Warrants may be (i) in cash or (ii) in the event that there is no registration statement available for the resale of Warrant shares, by cashless exercise.

Under the terms of the Warrants, the Company shall not effect the exercise of any portion of any Warrant, and 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 common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may, upon written notice to the Company, increase or decrease such percentage to any other percentage not in excess of 19.99%; provided that any increase or decrease in such percentage will not be effective until 61 days after such notice is delivered to the Company.

The Company has assessed the Warrants for appropriate equity or liability classification and determined the 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, Derivatives and Hedging ("ASC 815"). The 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 Warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The Warrants were initially recognized at their relative fair value in the amount of $741 at the time of issuance determined using Black-Scholes option-pricing model and will not be remeasured.

Reverse Stock Split

The Company's stockholders approved a reverse stock split of the Company's common stock on June 15, 2022. The Company effected the Reverse Stock Split on November 10, 2022. Pursuant to the Reverse Stock Split, every 20 shares of the Company's issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. The Reverse Stock Split reduced the authorized number of shares of common stock from 300,000,000 to 15,000,000 and, pursuant to the certificate of amendment, such reduced authorized number of shares of common stock was subsequently multiplied by three, such that following the Reverse Stock Split the Company has 45,000,000 shares of

common stock authorized. The Reverse Stock Split affected all issued and outstanding shares of the Company's common stock, and the respective numbers of shares of common stock underlying the Company's outstanding stock options, outstanding warrants and the Company's equity incentive plans were proportionately adjusted. All share and per share amounts disclosed give effect to the Reverse Stock Split on a retroactive basis.

As of December 31, 2023, 4,885,512 shares of common stock were issued and outstanding, no shares were held in treasury, and 24,610 shares of Series X Preferred Stock were issued and outstanding. In addition, as of December 31, 2023, there were:

- 24,847,000 shares of common stock reserved for issuance upon conversion of the Series X Preferred Stock;
- 2,212,102 shares of common stock issuable upon the exercise of options under existing equity incentive plans, of which 1,780,459 options were assumed through the Lung Acquisition;
- 416,617 and 7,500 shares of common stock reserved for issuance under the 2021 Plan and 2017 Employee Stock Purchase Plan, respectively, as well as any automatic increases in the number of shares of the common stock reserved under these plans; and
- 3,726,696 shares of common stock reserved for issuance upon exercise of outstanding warrants. The warrants consist of (i) warrants to purchase 646,759 shares of the Company's common stock, with an exercise price of $40.00 per share, which were issued in the April 2019 private placement, which expire on April 2, 2024; (ii) 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, and (iii) warrants to purchase 2,353,500 shares of the Company's common stock, which were issued and sold in the Financing as described above.

Accordingly, as of December 31, 2023, out of the 45,000,000 shares of common stock presently authorized, 36,095,427 shares are issued and outstanding or reserved for issuance and 8,904,573 shares of common stock remain available for future issuance.

13. Stock-Based Awards

As of December 31, 2023, the Company had five equity compensation plans, each of which was approved by its stockholders: 2006 Equity Incentive Plan, as amended (the "2006 Plan"), 2016 Stock Incentive Plan (the "2016 Plan"), 2017 Stock Incentive Plan (the "2017 Plan"), 2021 Stock Incentive Plan (the "2021 Plan"), and 2017 Employee Stock Purchase Plan (the "2017 ESPP"). The Company also assumed Lung's 2013 Long-Term Incentive Plan (the "2013 Plan") as a result of the Lung Acquisition.

As of December 31, 2023, the Company had 9,482 shares to be issued upon exercise of outstanding options under the 2006 Plan; 8,404 shares to be issued upon exercise of outstanding options under the 2016 Plan, and 130,903 shares to be issued upon exercise of outstanding options under the 2017 Plan. No outstanding options under the 2006 Plan, the 2016 Plan, or the 2017 Plan as of December 31, 2023. As such, no shares remained available for future issuance under the 2006 Plan, the 2016 Plan, or the 2017 Plan as of December 31, 2023.

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. 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 Company's Board of Directors (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 840,254 as of December 31, 2023, of which 416,617 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.

2017 Stock Incentive Plan

The 2017 Plan was approved by the Company's stockholders on June 16, 2017, and became effective on June 28, 2017. Under the 2017 Plan, the Company could 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 were eligible to receive awards under the 2017 Plan; however, incentive stock options could only be granted to employees. The 2017 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 granted, exercise prices, vesting and other restrictions were determined at the discretion of the Board, or its committee if so delegated.

Stock options granted under the 2017 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 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.

As of the effective date of the 2021 Plan, the Board determined to grant no further awards under the 2017 Plan.

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.

2017 Employee Stock Purchase Plan

On June 16, 2017, the Company's stockholders approved the 2017 ESPP, which became effective on June 28, 2017. Under the 2017 ESPP, the number of shares of common stock that may be issued under the 2017 ESPP will automatically increase on each January 1, beginning with the fiscal year ended December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 31,120 shares, (ii) 1% of the outstanding shares of common stock on such date and (iii) an amount determined by the Company's Board. On January 1, 2023 and January 1, 2024, no additional shares were reserved for issuance under the 2017 ESPP pursuant to this provision. 7,500 shares remained available for future issuance under the 2017 ESPP as of December 31, 2023.

2013 Stock Incentive Plan

The Company assumed the Lung's 2013 Plan as a result of the Lung Acquisition. In October 2013, Lung's Board of Directors ("Lung's Board") approved the 2013 Plan to provide long-term incentives for its employees, non-employee directors and certain consultants. As of December 31, 2023, 1,780,459 shares were reserved to be issued upon exercise of options outstanding under the 2013 Plan, and 726,437 shares to be issued upon exercise of outstanding warrants under Lung's 2013 Plan. These options and warrants were assumed by the Company in connection with the Lung Acquisition.

Before the Lung Acquisition, the 2013 Plan was administered by the Lung's Board or, at the discretion of the Lung's Board, by a committee of the Lung's Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Lung's 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 vesting periods for equity awards are determined by the Board, but generally are four years. The contractual term for stock option awards is ten years. The vesting periods for equity awards were determined by Lung's Board, but generally are 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 years ended December 31, 2023 and 2022 and at the Lung Acquisition date were as follows, presented on a weighted average basis:

	Year Ended December 31,		October 31,
	2023	2022	2023
Risk-free interest rate	4.90%	2.50%	4.82-5.58%
Expected term (in years)	4.0	6.1	0.42-6.28
Expected volatility	94.4%	94.2%	75-91%
Expected dividend yield	0%	0%	0%

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	537,112	$ 29.77	7.9	$ —
Granted	10,900	1.17	—	—
Exercised	—	—	—	—
Forfeited/Canceled	(57,483)	14.29	—	10
Expired	(58,886)	27.35	—	—
Options assumed through business combination	1,780,459	1.61	6.8	200
Outstanding at December 31, 2023	2,212,102	$ 7.42	6.0	$ 2,905
Options exercisable at December 31, 2023	1,882,191	$ 7.46	5.8	$ 2,631
Options vested and expected to vest at December 31, 2023	2,209,420	$ 7.41	6.0	$ 2,904
Options exercisable at December 31, 2022	288,821	$ 40.15	7.1	$ —
Options vested and expected to vest at December 31, 2022	529,549	$ 29.95	7.8	$ —

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2023 was $0.80. The weighted average grant-date fair value of stock options granted during the year ended December 31,

2022 was $7.32. The aggregate fair value of stock options that vested during the years ended December 31, 2023 and 2022 was $1,191 and $2,808, 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. There were no options exercised during the year ended December 31, 2023. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 was $0.

Stock-Based Compensation

The Company recorded stock-based compensation expense related to stock options in the following expense categories of its statements of operations and comprehensive loss:

	Year Ended December 31,	
	2023	2022
Research and development expenses	$ 277	$ 600
General and administrative expenses	913	1,483
	$ 1,190	$ 2,083

As of December 31, 2023, the Company had an aggregate of $1,702 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 1.73 years.

14. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows**:**

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (15,732)	$ (27,329)
Denominator:		
Weighted average common shares outstanding—basic and diluted	4,598,715	4,539,318
Net loss per share attributable to common stockholders—basic and diluted	$ (3.42)	$ (6.02)

The Company's potential dilutive securities, which include stock options as of December 31, 2023 and 2022, 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,	
	2023	2022
Options to purchase common stock	2,212,102	537,112
Warrants to issue shares of common stock	3,726,696	646,759
Series X Preferred Stock issued and outstanding, as converted	24,610,000	—
Total	30,548,798	1,183,871

15. Commitments and Contingencies

Operating Leases

On March 26, 2021, the Company entered into a sublease agreement (the "Sublease") by and among the Company, Vittoria Industries North America, Inc. (the "Sublessor") and Waterfront Equity Partners, LLC (the "Lessor"), under which the Company was leasing approximately 3,365 square feet of office space located at 285 Summer Street, Unit 101, Boston, Massachusetts (the "Premises"). The Sublease was subject and subordinate to a lease agreement, dated as of July 13, 2012, by and between the Sublessor and Lessor, pursuant to which the Sublessor is leasing the Premises from the Lessor. The Sublease expired March 31, 2023, and the Company did not renew the Sublease. Following expiration of the Sublease, the Company is operating virtually, and expects to do so in the foreseeable future.

On August 16, 2021, Lung Therapeutics 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 agreement is for a 30-month term that ended on March 31, 2024, and includes a rent escalation clause and a rent holiday. In addition to the base rent, the Company was also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the lease agreement. Following expiration of the lease, the Company expects to operate virtually for the foreseeable future.

The Company recognizes rent expense on a straight-line basis throughout the remaining term of the lease.

The following table contains a summary of the lease costs recognized and other information pertaining to the Company's operating leases for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Lease cost		
Operating lease cost	$ 184	$ 125
Total lease cost	$ 184	$ 125
Other Information		
Cash paid for amounts included in the measurement of lease liabilities	$ 192	$ 143
Weighted average remaining lease term (in years)	0.2	0.3
Weighted average discount rate	7%	12%

As of December 31, 2023, future minimum commitments under the Company's operating leases were as follows:

	2023
2024	$ 48
2025 and thereafter	-
Total lease payments	48
Less: imputed interest	-
Total operating lease liabilities	$ 48

Legal Proceedings

The Company may from time to time be party to litigation arising in the ordinary course of business. As of December 31, 2023 and 2022, the Company was not party to any legal proceedings and no material legal proceedings are currently pending or, to the best of 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 ("Harvard") and Dana-Farber Cancer Institute ("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 (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. Any payments made in connection with the annual license maintenance fees will be credited against any royalties due.

The Company incurred license maintenance fees of $35 and $110 during each of the years ended December 31, 2023 and 2022, respectively. In addition, the Company did not make any milestone payments during the years ended December 31, 2023 and 2022. During the years ended December 31, 2023 and 2022, no milestones were achieved and no liabilities for milestone payments were recorded in the Company's consolidated financial statements. From 2010 through December 31, 2023 and December 31, 2022, the Company had made non-refundable cash payments, consisting of license and maintenance fees, milestone payments and sublicense fees, totaling $5,153 and $5,118, respectively.

As of December 31, 2023, 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.

Umicore Agreement

In December 2006, the Company entered into a license agreement with Materia, Inc. ("Materia"), under which it was granted a non-exclusive worldwide license, with the right to sublicense, under specified patent and patent applications to utilize Materia's catalysts to develop, obtain regulatory approval for and commercialize specified peptides owned or controlled by Materia and the right to manufacture specified compositions owned or controlled by Materia. In February 2017, Materia assigned the license agreement (the "Umicore agreement") to Umicore Precious Metals Chemistry USA, LLC ("Umicore"), and Umicore agreed to continue to supply the Company under the agreement.

The Company incurred license fees of $50 during each of the years ended December 31, 2023 and 2022. The Company did not make any milestone payments during the years ended December 31, 2023 and 2022. During the year ended December 31, 2023, no milestones were achieved and no liabilities for additional milestone payments were recorded in the Company's consolidated financial statements.

The Umicore Agreement terminated in July 2023 with the expiration of the last patent the Company had licensed.

Agreement with the University of Texas Health Science Center at Tyler

In June 2013, Lung 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 University of Texas Health Science Center at Tyler, or UTHSCT. The patent and technology license agreement with UT System, or the UTHSCT Agreement, provides Lung access to patents and technology related to the development of LTI-01 and LTI-03. As part of the UTHSCT Agreement, Lung 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 Lung 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, Lung granted UT System (via UTHSCT and UT Horizon Fund affiliates) (i) 2,000,000 shares of Lung common stock and (ii) 400,000 shares of Lung non-convertible preferred stock. On February 6, 2015, UT System exchanged the 400,000 shares of Lung non-convertible preferred stock for 4,000,000 shares of Lung common stock. In addition, Lung agreed to pay past and ongoing patent expenses, and Lung 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, Lung 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.

Agreement with the University of Texas at Austin

In May 2015, Lung entered into a patent license agreement with UT Austin on behalf of the 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 Lung 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 Lung 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, Lung 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 an FDA Priority Review Voucher fee if Lung sells or transfers this voucher.

Pursuant to the UT Austin 6607 Agreement, Lung is required to use diligent efforts to commercialize the licensed products, including maintaining active research and development, regulatory, marketing and sales program. Moreover, Lung 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.

Agreement with Medical University of South Carolina

In March 2016, Lung 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, Lung 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 Lung 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, Lung 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 Lung's liquidation.

Pursuant to the MUSC Agreement, Lung 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.

Agreement with Vivarta Therapeutics LLC

In March 2018, Lung 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 Lung 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 Lung 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, Lung agreed to grant Vivarta a warrant to purchase an aggregate of 75,000 shares of Lung common stock 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. Lung 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, Lung 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.

Manufacturing Commitments

As of December 31, 2023, the Company has non-cancellable purchase obligations and a prepaid balance with its contract manufacturer in the amount of $2,312 and $1,432, respectively.

Aggregate future service and purchase commitments with manufacturer as of December 31, 2023 are as follows:

	2023
2024	$ -
2025 and thereafter	2,312
Total purchase commitments	2,312

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, 2023 or December 31, 2022.

16. Income Taxes

On October 31, 2023, the Company acquired, in accordance with the terms of the Lung Acquisition Agreement, the stock of Lung Therapeutics ("Target"). In accordance with ASC 805-740-25-3, 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 740-10-55-63 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 no income tax expense or benefit for the year ended December 31, 2023. 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.

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,	
	2023	2022
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	108.1	(5.4)
Research and development and orphan drug tax credits	31.5	(2.9)
Other permanent items	2.4	0.9
Change in deferred tax asset valuation allowance	(444.9)	28.4
Loss of federal net operating losses due to 382	323.9	—
Effective income tax rate	—%	—%

Net deferred tax liabilities as of December 31, 2023 and 2022 consisted of the following:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 12,387	$ 64,959
Research and development and orphan drug tax credit carryforwards	7,825	6,606
Capitalized research and development expenses	9,797	4,380
Accrued expenses and reserves	251	61
Depreciation and amortization	—	—
Lease liability	10	9
Stock compensation	1,514	1,442
Total deferred tax assets	31,784	77,457
Valuation allowance	(18,506)	(77,441)
Net deferred tax assets	$ 13,278	$ 16
Deferred tax liabilities:		
Depreciation and amortization	$ (16,594)	$ (5)
Right of use asset	$ (10)	$ (11)
Total deferred tax liabilities	$ (16,604)	$ (16)
Net deferred tax asset (liability)	$ (3,326)	$ —

As of December 31, 2023, the Company had net operating loss carryforwards for federal and state purposes of $56,518 and $8,197, respectively. $2,863 of the U.S. federal tax operating loss carryforwards will begin to expire in 2036. Approximately $53,655 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, 2023, the Company also had available research and development tax credit carryforwards for federal income tax purposes of $1,094, which begin to expire in 2035. As of December 31, 2023, the Company also had available orphan drug credit carryforwards of $6,731 for federal income tax purposes, which begin to expire in 2039. Of this amount, $1,064 of research and development credit carryforwards and $6,574 of orphan drug credit carryforwards came over from the Lung Acquisition.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense research and development expenditures. Taxpayers are now required to capitalize and amortize these costs over 5 years for research conducted within the United States or 15 years for research conducted abroad. As a result, the Company capitalized $3,639 of research and development expenses for the year ended December 31, 2023 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. The remaining net operating losses and tax credits as of December 31, 2023 relate to post-merger activity in the year, as well as acquired attributes as part of the merger in the year. 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,

2023, the total federal net operating losses are $56,518 and federal research and development tax credits are $7,825, 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, 2023. Management reevaluates the positive and negative evidence at each reporting period. The decrease in the valuation allowance relates primarily to the deferred tax liability recognized as a result of the transaction as well as the reduction in prior year deferred tax assets due to Section 382 limitations. The increase in the valuation allowance for deferred tax assets during the year ended December 31, 2023 related primarily to an increase in net operating loss carryforwards. Changes in the valuation allowance were as follows:

	Year Ended December 31,	
	2023	2022
Valuation allowance at beginning of year	$ (77,441)	$ (69,680)
Decreases/(increases) recorded to income tax provision	69,134	(7,761)
Increases recorded to invested capital	(10,199)	—
Valuation allowance at end of year	$ (18,506)	$ (77,441)

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2023 or 2022.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. 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 2019 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, 2023 and 2022, 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.

17. Related Party Transactions

Immediately following the closing of the Lung Acquisition, the Company entered into the Purchase Agreement with a group of accredited investors led by Bios Partners, the majority stockholder of Lung prior to the closing of Lung Acquisition, and including Nantahala Capital, as well as additional undisclosed investors, pursuant to which the Company issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) up to an aggregate of 2,353,500 Warrant Shares, as described in the Note 3, which included the conversion of convertible promissory notes in the aggregate principal amount of $1,553 issued by Lung to Bios Partners prior to the closing of the acquisition at a 10% discount to the per share price of Series X Preferred Stock. The Financing closed on November 2, 2023.

18. Subsequent Event

On February 28, 2024, the Company held its 2023 annual meeting of stockholders (the "2023 Annual Meeting") at which the stockholders of the Company approved an amendment (the "Plan Amendment") to the Aileron's 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. On January 17, 2024, upon the recommendation of the compensation committee and subject to stockholder approval, the Company's Board of Directors adopted the Plan Amendment. Other than increasing the number of shares issuable under the 2021 Plan, the Plan Amendment does not make any changes to the 2021 Plan. The material terms of the 2021 Plan are described in the Company's definitive proxy statement for the 2023 Annual Meeting filed with the Securities and Exchange Commission on January 29, 2024 (the "Proxy Statement").

At the 2023 Annual Meeting, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock of the Company from 45,000,000 to 100,000,000 shares. The Company filed the Certificate of Amendment to implement

the increase in the number of authorized shares, which was effective upon filing, with the Secretary of State of the State of Delaware on February 28, 2024. The additional shares of common stock authorized by the Certificate of Amendment have rights identical to the Company's currently outstanding Common Stock.

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. Following approval of the conversion of outstanding Series X Preferred Stock, the Company had 29,495,512 shares of common stock issued and outstanding on a pro forma basis, which gives effect to the full conversion of the Series X Preferred Stock as of the date of the 2023 Annual Meeting, without regard to beneficial ownership limitations that may limit the ability of certain holders of Series X Preferred Stock to convert such shares to common stock as such time. On March 5, 2024, based upon existing beneficial ownership limitations, 12,087 shares of Series X Preferred Stock were automatically converted into 12,087,000 shares of common stock. The remaining approximately 12,523 shares of Series X Preferred Stock (which are convertible into 12,523,000 shares of common stock) will remain convertible at the option of the holder thereof, subject to certain beneficial ownership limitations.

On February 29, 2024, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company that it has regained compliance with the annual meeting requirement for continued listing on the Nasdaq Capital Market set forth in Nasdaq Listing Rule 5620.

On March 11, 2024, the Company and Manuel C. Alves-Aivado, M.D., Ph.D., agreed that his employment with the Company would cease and he would resign from his position as Chief Executive Officer of the Company, effective as of March 11, 2024 (the "Separation Date"). Dr. Aivado will remain a member of the Company's Board. Dr. Aivado's resignation from the Company was not the result of any disagreement with the Company on any matter relating to its operations, policies or practices.

In connection with Dr. Aivado's separation from the Company, and in accordance with the severance agreement, dated as of September 6, 2018, between the Company and Dr. Aivado, Dr. Aivado is entitled to receive his base salary for eighteen months of $881 following the separation date, payments on Dr. Aivado's behalf of the monthly premiums for medical insurance coverage under COBRA until the earlier of the date that is eighteen months following the separation date or the date on which Dr. Aivado becomes eligible to receive group health insurance coverage through another employer, a lump sum payment of $441 equal to one and one-half times Dr. Aivado's target bonus for the 2024 calendar year, and acceleration in full of the vesting of any unvested equity awards. Dr. Aivado's receipt of these post-separation benefits under the severance agreement is conditioned upon his execution of a severance and release of claims agreement with the Company.

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